EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	C.A. No. 21-1286 (MSG)
v.	)	C.A. No. 21-1455 (MSG)
	)	
BIONPHARMA INC.,	)	
	)	
Defendant.	)	

[PROPOSED] STIPULATED PROTECTIVE ORDER

Plaintiff Azurity Pharmaceuticals, Inc. ("Plaintiff" or "Azurity"), and Defendant Bionpharma, Inc. ("Bionpharma") (Plaintiff and Defendant together, "Parties" and both individually, a "Party") assert that they possess confidential information in the form of trade secrets or other confidential business, commercial, personal, proprietary, and/or technical information related to the subject matter of Civil Action Nos. 21-1286 and 21-1455 (individually, an "Action" and collectively, "Actions"). These above-captioned Actions concern patent disputes relating to United States Patent Nos. 11,040,023 ("'023 Patent") and 11,141,405 ("'405 Patent") (collectively, "Patents-in-Suit"). The Parties recognize that it may be necessary to disclose certain confidential information during the course of these Actions, and contemplate that non-parties may produce confidential information. Pursuant to Federal Rules of Civil Procedure ("Fed. R. Civ. P.") 26(c), and for good cause shown, the Parties, by and through their respective undersigned counsel, hereby stipulate and consent to the entry of this Stipulated Protective Order ("Protective Order").

1. Definitions and Scope

(a) "Discovery Material" means any document, material, item, testimony, or thing filed with or presented to the Court or produced, served, or generated during the discovery process, including but not limited to exhibits, answers to interrogatories, responses to requests for

admissions, responses to requests for production, subpoenas, declarations, affidavits, deposition testimony or transcripts, and all copies, extracts, summaries, compilations, designations, and portions thereof.

(b) Discovery Material designated as "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER" by a Producing Party means such Discovery Material comprises or contains highly sensitive and/or proprietary technical, commercial, financial, or business information including without limitation:

(i) trade secrets, ownership, management, corporate structure or organization, business and/or strategic plans, financial planning or performance, budgeting, advertising expenditures, accounting, decisions and/or processes, license agreements, negotiations, sales projections, profit projections, market share projections, pricing plans and pricing analysis, non-public sales data and analysis, non-public market share data, and non-public documents, materials, or information relating to present or prospective customers, dealers, and distributors (such as proposals, bids or contracts), current or future, the disclosure of which could result in severe competitive or commercial disadvantage to the Producing Party;

(ii) as purporting to cover enalapril maleate oral solutions: non-public patent applications and files; non-public research, development, formulation, manufacture, testing, or evaluation of pharmaceuticals; approved or unapproved (whether pending or not yet filed) New Drug Applications ("NDA") or Abbreviated New Drug Applications ("ANDA"); non-public

communications with the United States Food and Drug Administration ("FDA");

(iii) information received under confidentiality restrictions or an agreement from vendors, suppliers, and/or third parties;

(iv) private or confidential personal information, patient information, or personal health information including information protected under the Health Insurance Portability and Accountability Act of 1996;

(v) drafts, attachments, or internal communications related to the foregoing.

HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER Discovery Material may be disclosed only to the individuals identified in Paragraph 5 below.

(c) "Designated Material" means any Discovery Material designated by a Producing Party as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER. Each Party shall act reasonably and in good faith in designating Discovery Material as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER.

(d) "Producing Party" means any Party to the Actions or any non-party, including its counsel, retained experts and consultants, third party testing laboratories, directors, officers, employees, or agents, who produces any Discovery Material in the Actions.

(e) "Receiving Party" means any Party to the Actions, including its counsel, retained experts and consultants, third party testing laboratories, directors, officers, employees, or agents, who receives any Discovery Material in the Actions.

(f) This Protective Order encompasses not only Discovery Material that is expressly designated HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER, but also any information derived therefrom, including all copies, excerpts, and summaries thereof, whether

partial or complete, as well as testimony and oral conversations that reveal all or part of such information, and any other discovery taken or disclosures provided pursuant to the Federal Rules of Civil Procedure or District of Delaware Local Rules.

2. Procedure for Marking and Designating Discovery Material

Marking Discovery Material as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER shall be made by the Producing Party in the following manner:

(a) In the case of documents or any other tangible thing produced, designation shall be made by placing the legend "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER" on each page of the document, or on the cover, or in a prominent place on any other tangible thing prior to production of the document or tangible thing.

(b) In producing original files and records for inspection, no marking need be made by the Producing Party in advance of the inspection. For the purposes of the inspection, all documents produced for inspection shall initially be considered as marked "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER." Thereafter, upon selection of specified documents for copying by the Receiving Party, the Producing Party shall mark such Designated Material as "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER" based on the definitions discussed in Paragraph 1(b).

(c) In the case of deposition testimony, transcripts, or portions thereof, designation shall be made by the Producing Party as follows:

(i) on the record during the deposition, in which case the portion of the transcript of the designated testimony shall be bound in a separate volume and marked "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER" by the reporter;

(ii) by written notice to the reporter and all counsel of record, given within thirty (30) calendar days after the reporter sends written notice to the deponent or the deponent's counsel that the transcript is available for review, in which case all counsel receiving the notice shall be responsible for marking the copies of the designated transcript or portion(s) thereof in their possession or control as directed by the Producing Party or deponent; or

(iii) by written notice to the reporter and all counsel of record, given within thirty (30) calendar days after reporter sends written notice to the deponent or the deponent's counsel that the transcript is available for review, that certain portions can be re-designated as not confidential. Pending expiration of the thirty (30) calendar days, all Parties and, if applicable, any third-party witnesses or attorneys, shall treat the deposition transcript as if it had been designated "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER."

No person shall attend the portions of depositions designated HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER unless that person is an authorized recipient of material designated HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER pursuant to the terms of this Protective Order or the Parties agree to that person's attendance.

3. Challenging Designations

(a) No Party to these Actions shall be obligated to challenge the propriety of any designation by any Producing Party, and a failure to do so shall not constitute a waiver or in any way preclude a later challenge to the propriety of the designation in these Actions.

(b) Any Party may contest a claim of confidentiality. Any Party objecting to the designation of any Discovery Material as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER must serve outside counsel of record for the Producing Party written notice of its reasons, described with particularity, for the objection, and identify the information, preferably by production number. Counsel for the Producing Party shall respond in writing to such objection within five (5) business days[1] and shall state with particularity the grounds for asserting that the Discovery Material is HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER.

(c) Failing resolution after ten (10) business days from service of the objecting Party's written notice of reasons for objection, the objecting Party may seek an order changing or removing the designation. In resolving the matter, the burden of establishing confidentiality shall be on the Party who made the claim of confidentiality, *i.e.*, the Producing Party, but information designated as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER shall be deemed so designated until the matter is resolved.

4. Restrictions on Disclosure and Use

(a) CONFIDENTIALITY

Designated Material and the information derived from the Designated Material (excluding information which is derived lawfully from an independent source) shall not be given, shown, made available, discussed, or otherwise communicated in any manner, to any person not authorized to receive the information pursuant to the terms of this Protective Order, unless and to the extent that this Protective Order is otherwise modified by court order. Any summary,

[1] A "business day" is a day on which the Clerk's Office of the United States District Court for the District of Delaware is open.

compilation, notes, memoranda, analysis, electronic image, or database containing Designated Material shall be subject to the terms of this Protective Order to the same extent as the material or information from which the summary, compilation, notes, memoranda, analysis, electronic image, or database is derived.

(b) RESTRICTIONS ON USE

Absent an agreement of the Producing Party or an order to the contrary by this Court, each Party and all other persons bound by the terms of this Protective Order shall use any material designated as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER solely for purposes of these Actions and any appeal therefrom. Such Designated Material shall not be used for any other purpose, including, without limitation, any business, commercial, competitive, personal, or other purpose.

Specifically, HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER material obtained from these Actions shall not be submitted, used, or relied upon to prepare submissions to the U.S. Food and Drug Administration ("FDA") or U.S. Patent and Trademark Office ("USPTO"). Counsel of record for the parties shall exercise reasonable care to ensure that the information and documents governed by this Protective Order are (i) used only for the purpose specified herein, and (ii) disclosed only to authorized persons.

Absent consent of the Producing Party or further order of this Court, all outside counsel of record as defined in Paragraph 5(a) who are substantively involved in the drafting or prosecution of claims in patents and/or patent applications relating to the Patents-in-Suit (including any continuations, continuations-in-part, or divisionals thereof claiming enalapril maleate oral solutions, or processes for making enalapril maleate oral solutions, or methods of treatment involving enalapril maleate oral solutions) will not have access to any documents containing the

formulation for Bionpharma's product produced pursuant to ANDA No. 212408 ("Bionpharma Formulation Material"). For avoidance of doubt, the Bionpharma Formulation Material is information that discloses the entirety of Bionpharma's qualitative formulation, or the amount or concentration of any excipient contained in Bionpharma's ANDA product.. For the avoidance of doubt, being "substantively involved in the drafting or prosecution of claims in patents and/or patent applications" in the previous sentence shall mean the drafting or amending of claims, or providing direction or input on the drafting or amending of claims. Outside counsel of record as defined in Paragraph 5(a) who do have access to Bionpharma Formulation Material cannot participate in such aforementioned activities during the pendency of these Actions, including any appeals therefrom, and for twelve (12) months after the last of these Actions is finally terminated.

For clarity, nothing in this agreement prohibits persons with access to HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER information from participating in opposition, reexamination, *inter partes* review, or other post-grant proceedings (except reissue) before the USPTO or before any foreign patent-granting authority (collectively, "Post-Grant Proceedings"). However, no outside counsel of record as defined in Paragraph 5(a) who do have access to Bionpharma Formulation Material shall draft or provide any input on the drafting and/or amendment of claims in any Post-Grant Proceeding pertaining to enalapril maleate oral solutions during the pendency of these Actions, including any appeals therefrom, and for twelve (12) months after these Actions are terminated, but such outside counsel of record as defined in Paragraph 5(a) and in-house representatives may otherwise fully participate in all such Post-Grant Proceedings pertaining to enalapril maleate oral solutions.

For the avoidance of doubt, outside counsel who do not have access to Bionpharma Formulation Material under this Protective Order are not restricted in any manner by this

Paragraph 4(b), and for example, may therefore freely draft, amend, and/or prosecute claims before the USPTO or before any foreign patent-granting authority. For the further avoidance of doubt, outside counsel who do not have "access" to Designated Material under this Protective Order means that such persons have not received Designated Material and will not attempt to obtain or view such Designated Material within the outside counsel firm's servers or other storage locations. All outside counsel of record in these Actions are presumed to have "access" to Designated Material as that term is used in this Paragraph and are subject to the restrictions of this Paragraph 4(b).

(c) MAINTENANCE OF DESIGNATED MATERIAL

Designated Material shall be maintained by the Receiving Party at a location and under circumstances to ensure that access is limited to only those persons entitled to have access pursuant to this Protective Order.

A Producing Party is free to do whatever it desires with its own Designated Material.

5. Access to Designated Material

Designated Material shall be available only to the following persons subject to the terms of Paragraph 6:

(a) Outside counsel of record to any Party in connection with these Actions, and the outside counsel's partners, associates, attorneys, data entry, information processing, computer support, artist, translating, stenographic, clerical, and paralegal employees or agents whose duties and responsibilities require and who actually have access to materials designated "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER," subject to the restrictions set forth in Paragraph 4(b).

(b) The Court, including Judges, Magistrate Judges, law clerks, and clerical personnel of the Court before which these Actions are pending, and qualified court reporters;

(c) Approved consultants or experts and their staff, but excluding employees, officers, or directors of a named Party, retained by any of the Parties or their counsel to consult or testify in these Actions subject to the terms of Paragraph 6(a);

(d) Authors or drafters; addressees; anyone else who received the documents or information prior to the commencement of these Actions, or during these Actions, but only if they obtained the document or information outside of these Actions and not in violation of this Protective Order; provided that, in the case of former employees/consultants of the Producing Party permitted access pursuant to this provision, (i) the former employee/consultant reviews this Protective Order and executes the Agreement to be Bound by Protective Order, in the form shown in Exhibit A, which is attached hereto, prior to receiving Designated Material, (ii) the former employee/consultant of the Producing Party is not employed or retained by the Receiving Party, and (iii) Designated Material is shared with the former employee/consultant of the Producing Party only during a deposition taken in these Actions.

(e) Third party contractors and their employees involved in document management or copying services for these Actions;

(f) Graphics or design services retained by counsel for a Party for purposes of preparing demonstratives or other exhibits for deposition, trial, or other court proceedings in these Actions;

(g) Trial consulting services retained by a Party in these Actions;

(h) Persons who have been retained by a Party to provide translation or interpretation from one language to another;

(i) Third party testing laboratories and their staffs retained by any of the parties or their counsel for purposes of these Actions subject to the terms of Paragraph 6(b); and

(j) Any other person authorized to receive HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER Designated Material by order of the Court or by written agreement of the parties;

(k) Two (2) designated in-house representatives for each Party who have responsibility for maintaining and/or overseeing these Actions, as well as their secretarial and clerical staff. Such representatives must execute a copy of the Agreement to be Bound by Protective Order (Exhibit A) prior to being given access to material designated as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER.

(l) Azurity's in-house representatives as indicated in paragraph 5(k) are permitted to receive Designated Material produced by Bionpharma (upon execution of a copy of the Agreement to be Bound by Protective Order (Exhibit A)), and will be permitted access to Designated Material produced by Bionpharma pursuant to the restrictions contained in this Order. However, Azurity's in-house counsel will not have access to any documents containing Bionpharma Formulation Material. All Bionpharma Formulation Material will be redacted in any document prepared for purposes of this litigation prior to sending to the in-house representatives indicated in paragraph 5(k).

6. Conditions on Access to Designated Material

(a) CONSULTANTS AND EXPERTS

Prior to a Receiving Party giving, showing, disclosing, making available, or communicating Designated Material to any expert or consultant under Paragraph 5(c), the Receiving Party shall:

(i) Provide written notice to the Producing Party identifying the expert or consultant and the following information:

(A) The expert's or consultant's business address, present employer and position (including a job description), and job history;

(B) a list of prior consulting relationships for companies involved in the development, manufacturing, marketing or sale of pharmaceutical products for the past five (5) years;

(C) the case name, number, and location of the court for any litigation in connection with which the expert or consultant has offered expert testimony, including through a declaration, report, or testimony at a deposition or trial, during the preceding five (5) years; and

(D) past or present relationship, if any, with the Receiving Party and/or Producing Party.

(E) Furthermore, the most recent curriculum vitae or resume of the expert or consultant shall be provided pursuant to this section. If the most recent curriculum vitae or resume of the expert or consultant provides the information required pursuant to this Paragraph, then the information need not be separately provided.

(ii) Include with the notice, a copy of Agreement to be Bound by Protective Order (Exhibit A), signed by the expert or consultant.

(iii) The Producing Party shall be entitled to object to any disclosure of Designated Material to the expert or consultant within five (5) business days after receipt of the Agreement to be Bound by Protective Order by stating

specifically in writing the reasons why the identified expert or consultant should not receive the Designated Material. Proper objectionable grounds include but are not limited to:

(A) The proposed expert or consultant is currently employed or anticipates future employment by Plaintiff or Defendant(s);

(B) The proposed expert or consultant is performing work-related to any product that is the subject of the Patents-in-Suit separate and apart from the work performed in connection with these Actions;

(C) The proposed expert or consultant is performing work related to any pharmaceutical drug product designed to directly compete with the products involved in these Actions.

(iv) If the Parties are unable to agree on disclosure of Designated Material to the expert or consultant, the objecting Party may apply to the Court for an order that disclosure is improper within ten (10) calendar days of its objection. The burden of establishing the validity of written objections rests with the objecting Party. If the objecting Party does not apply to the Court within the prescribed period, the objection shall be deemed withdrawn by using the procedure set forth in Paragraph 7(h) of the Scheduling Order (No. 21-1286, D.I. 126).

(v) No disclosure of the Designated Material shall be made to the proposed expert or consultant until the time for serving objections to that expert or

consultant has passed, or, in the event that a written objection is timely served and a submission to prevent disclosure is filed, until the Court has made a ruling thereon, and then, only in accordance with that ruling.

(vi) The filing and pendency of objections shall not limit, delay, or defer any disclosures of Designated Material to the expert or consultant as to whom no objection has been made, nor shall it delay or defer any other pending discovery unless the level of confidentiality bears directly on the objecting Party's ability to conduct that discovery.

(b) THIRD PARTY TESTING LABORATORIES

Counsel may use the services of third party testing laboratories to perform tests and analyses for the Actions on Designated Material marked HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER. Prior to a Receiving Party giving, showing, disclosing, making available, or communicating Designated Material to any third party testing laboratory pursuant to Paragraph 5(i) above, the Receiving Party shall:

(i) Provide written notice to the Producing Party, identifying the third party testing laboratory, the third party testing laboratory's business address, and past or present relationship, if any, the third party testing laboratory has/had with the Receiving Party and/or Producing Party.

(ii) Include with the notice a copy of the Agreement to be Bound by Protective Order (Exhibit A), signed by a representative of the third party testing laboratory.

(iii) The Producing Party shall be entitled to object to the disclosure of Designated Material to the third party testing laboratory within ten (10)

calendar days after receipt of the Acknowledgment of Protective Order by stating specifically in writing the reasons why the third party testing laboratory should not receive the Designated Material.

(iv) If the parties are unable to agree on the disclosure to the third party testing laboratory, the objecting Party may apply to the Court for an order that disclosure of Designated Material is improper within ten (10) calendar days of its objection. The burden of establishing the validity of written objections rests with the objecting Party. If the objecting Party does not apply to the Court within the prescribed period, the objection shall be deemed withdrawn by using the procedure set forth in Paragraph 7(h) of the Scheduling Order (No. 21-1286, D.I. 126).

(v) No disclosure of the Designated Material shall be made to the proposed third party testing laboratory until the time for serving objections to that third party testing laboratory has passed, or, in the event that a written objection is timely served and a submission to prevent disclosure is filed, until the Court has made a ruling thereon, and then, only in accordance with that ruling.

(vi) The filing and pendency of objections shall not limit, delay, or defer any disclosures of Designated Material to third party testing laboratories as to whom no objection has been made, nor shall it delay or defer any other pending discovery unless the level of confidentiality bears directly on the objecting Party's ability to conduct that discovery.

(c) AUTHORIZATION AND ACKNOWLEDGEMENT

Persons or firms retained by Plaintiff or Defendant(s) to whom Designated Material is to be given, shown, disclosed, made available, or communicated in any way in accordance with this Protective Order (excluding the Court, *e.g.*, Judges, Magistrate Judges, law clerks, qualified court reporters, and clerical personnel of the Court before which these Actions are pending; and outside counsel of record to any Party in connection with these Actions and the outside counsel's partners, associates, attorneys, data entry, information processing, computer support, artist, translating, stenographic, clerical, and paralegal employees or agents whose duties and responsibilities require access to materials designated HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER), shall first execute an Agreement to be Bound by Protective Order (Exhibit A). Counsel for the Receiving Party shall keep in his or her files an original of each executed Acknowledgment of Protective Order until sixty (60) calendar days after the final termination of these Actions.

7. Procedures for Filing Papers with Designated Material

Designated Material may be included with, or referred to in, papers filed with the Court where these Actions are now pending or in any other court only in accordance with the following procedures:

(a) The Designated Material must be filed under seal in accordance with the applicable procedures set forth in the Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware and any Orders of the Court.

(b) All papers filed with the Court, including but not limited to pleadings and memoranda of law, which include all or any portion of information set forth in Designated Material must be filed under seal in accordance with the terms and procedures set forth in this Order, including the procedures for filing materials set forth above in Paragraph 7(a). Counsel for the

Party filing papers with Designated Material shall be responsible for designating all papers filed with the Court as Designated Material and marked as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER depending on the contents of the papers being filed. The papers shall be subject to the terms of this Order.

8. Redacted Filings of Papers with Designated Material

Redacted versions of papers with Designated Materials filed under seal must be filed with the Court in accordance with the applicable procedures set forth in the Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware and any orders of the Court, and made publicly available provided that:

(a) All Designated Material set forth in the papers is deleted or obscured and all Designated Material is removed as exhibits; and

(b) Redacted versions of the papers are clearly marked "REDACTED PUBLIC VERSION" or a similar legend. Redacted versions of the papers also must clearly identify each place where information or exhibits have been deleted.

9. Unintentional Failure to Designate and Inadvertent Production

If, through inadvertence, regardless of reason or circumstances, a Producing Party provides any Designated Material in these Actions without designating and marking the Designated Material as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER, the Producing Party may subsequently inform the Receiving Party of the confidential nature of the disclosed Designated Material. The Receiving Party shall treat the disclosed Designated Material as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER upon receipt of written notice from the Producing Party, to the extent the Receiving Party has not disclosed this Designated Material to persons not authorized to receive that material under Paragraph 5.

Disclosure of Designated Material to persons not authorized to receive that material prior to receipt of the confidentiality designation shall not be deemed a violation of this Protective Order. However, in the event the material has been distributed in a manner inconsistent with the categorical designation, the Receiving Party promptly will take the steps reasonably necessary to (i) conform distribution to the categorical designation, *i.e.*, by retrieval and destruction of all copies of the Designated Material, or notes or extracts thereof, in the possession of the person(s) not authorized under this Protective Order to possess the Designated Material; (ii) advise the person(s) to whom disclosure was made that the material is confidential and should be treated as provided in the Protective Order, and (iii) confirm to the Producing Party in writing the retrieval or destruction. In the event the Receiving Party believes it has been prejudiced by any inadvertent failure to designate, the Receiving Party may contest the designation as set forth in Paragraph 3.

10. Privileged Information

The Parties agree that, as to objections based on attorney-client privilege, work product, or other immunity from discovery pursuant to Fed. R. Civ. P. 26 and Federal Rule of Evidence ("F.R.E.") 502, in response to requests for production pursuant to Fed. R. Civ. P. 34 and interrogatories pursuant to Fed. R. Civ. P. 33, to the extent that a Party is required at the time of making such objection to provide information identifying documents or information withheld from production because of objections based on privilege or immunity, the information shall be provided in the form of a privilege log at a mutually agreed upon time on or before the close of fact discovery. The Parties agree that production of a privilege log at the mutually agreed upon time shall not constitute waiver of the asserted privilege or immunity as to any document or information.

Counsel shall exert their best efforts to identify documents or material protected by the attorney-client privilege, the attorney work-product doctrine, the common-interest doctrine, or any other privilege or immunity prior to the disclosure of any documents or material. If, however, a Party unintentionally regardless of reason or circumstances, discloses documents or material that is privileged or otherwise immune from discovery, the Party shall, promptly upon discovery of the disclosure, so advise the Receiving Party in writing, request the documents or material be returned or destroyed, and attach a privilege log entry within twenty (20) calendar days pertaining to the documents or material that is privileged or otherwise immune from discovery. If that request is made and the privilege log provided, no Party to the Actions shall thereafter assert that the disclosure waived any privilege or immunity.

It is further agreed that the Receiving Party will return or destroy the inadvertently produced documents or material, and all copies and derivations (including any notes or work product made therefrom), within five (5) business days of the Receiving Party's receipt of a written request for the return of the documents or material. The Receiving Party having returned or destroyed the inadvertently produced documents or material may thereafter seek production of the documents or material in accordance with the Federal Rules of Civil Procedure, but cannot assert that the privilege has been waived due to the unintentional disclosure. These procedures are not intended to in any way limit the right of a Party to argue pursuant to F.R.E. 502 or any other law that any inadvertent production did not constitute a waiver, except that the Receiving Party shall not sequester or retain the inadvertently produced documents in any manner or for any purpose, including for purposes of challenging the privilege claim.

In the event that a Receiving Party, in good faith, believes that the document(s) or tangible item(s) that were withdrawn by the Party claiming privilege are not properly subject to a claim of

attorney-client privilege, work product immunity, or any other privilege or immunity, the Receiving Party may only use the privilege log as the basis for any motion to compel, and not the contested document. For the avoidance of doubt, the Court (including Judges, Magistrate Judges, law clerks, and clerical personnel of the Court before which these Actions are pending) is permitted to review the contested document in-camera in conjunction with a motion to compel.

11. Information Not Covered by Protective Order

The restrictions set forth in this Protective Order shall not apply to information which is in the possession of or otherwise known to the Receiving Party or the public before the date of its transmission to the Receiving Party, or which lawfully comes into the possession of or becomes known to the Receiving Party or lawfully comes into the possession of or otherwise becomes known to the public after the date of its transmission to the Receiving Party, provided that the information does not become publicly known by any act or omission of the Receiving Party which would be in violation of this Protective Order.

12. Responsibility of Attorneys

Outside counsel of record shall be responsible for providing a copy of this Protective Order to all persons entitled access to Designated Material under Paragraph 5 and to employ reasonable measures to control duplication of, access to, and distribution of copies of materials so designated. All copies, extracts and translations must be appropriately marked and are subject to Paragraph 13 of this Protective Order.

13. Final Disposition

Upon termination, settlement, or final judgment of these Actions, including exhaustion of all appeals, the originals and all copies of Designated Material shall be either destroyed or turned over to the Producing Party, or to their respective outside counsel, within ninety (90) calendar

days. However, outside counsel may retain court filings and other pleadings and discovery served; trial, deposition, and hearing transcripts; correspondence; expert reports; attorney and consultant work product; and deposition and trial exhibits for archival purposes. If Designated Material is destroyed pursuant to this Paragraph, outside counsel for the Receiving Party shall provide to outside counsel for the Producing Party a certification that the destruction was performed. The provisions of this Protective Order insofar as it restricts the disclosure, communication of, and use of Designated Material produced hereunder shall continue to be binding after the conclusion of these Actions.

14. No Limitation on Other Rights

This Protective Order shall be without prejudice to the right of any Party to oppose production of any information on any and all grounds other than confidentiality.

15. Release from or Modification of Protective Order

This Protective Order is entered without prejudice to the right of any Party to apply to the Court at any time for additional protection; or to release, rescind, or modify the restrictions of this Protective Order; to determine whether a particular person shall be entitled to receive any particular information; or to seek relief from inadvertent disclosure of privileged or work-product information. This Protective Order does not preclude all of the parties to this Protective Order from entering into any stipulation (in writing or on the record) constituting a modification of this Protective Order. On any application seeking disclosures beyond those authorized by this Protective Order, the burden will be on the Receiving Party to justify the disclosure.

16. Other Proceedings

By entering this Protective Order and limiting the disclosure of information in these Actions, the Court does not intend to preclude another court from finding that information may be

relevant and subject to disclosure in another case. Any person or Party subject to this Protective Order who becomes subject to a motion to disclose another Party's information designated HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER pursuant to this Protective Order in another case shall promptly notify that other Party of the motion so that the other Party may have an opportunity to appear and be heard on whether that information should be disclosed.

17. Discovery from Third Parties

If discovery is sought of a person not a Party to these Actions (*i.e.*, a third party) requiring disclosure of said third party's Designated Material, the Designated Material disclosed by the third party will be accorded the same protection as the parties' Designated Material, and will be subject to the same procedures as those governing disclosure of the parties' Designated Material pursuant to this Protective Order. Should a Party to these Actions have a good faith basis that the third party production may contain a Party's confidential information, that Party shall be allowed to designate that information according to this Protective Order within twenty-one (21) calendar days of receipt of that production.

18. Admissibility

Nothing herein shall be construed to affect in any way the evidentiary admissibility of any document, testimony, or other matter at any court proceeding related to the Action. The marking of Designated Material as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER pursuant to this Protective Order shall not, for that reason alone, bar its introduction or use at any court proceeding related to these Actions pursuant to the terms and conditions as the Court may deem appropriate, consistent with the need for a complete and accurate record of the proceedings, provided, however, that every effort shall be made, through the use of procedures agreed upon by the Parties or otherwise, to preserve the confidentiality of Designated Material.

19. Non-Party Request and/or Subpoena of Designated Material

If a Receiving Party receives a subpoena or other compulsory process from a non-party to this Protective Order seeking production or other disclosure of a Producing Party's Designated Material, that Receiving Party shall give written notice to outside counsel of record for the Producing Party within five (5) business days after receipt of the subpoena or other compulsory process identifying the specific Designated Material sought and enclosing a copy of the subpoena or other compulsory process. If the Producing Party timely seeks a protective order, the Receiving Party to whom the subpoena or other compulsory process was issued or served shall not produce the Designated Material requested prior to receiving a court order or consent of the Producing Party. In the event that Designated Material is produced to the non-party, the material shall be treated as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER pursuant to this Protective Order.

20. Unintentional Disclosure of Designated Material

If Designated Material, or any portion thereof, is disclosed by the Receiving Party, through inadvertence or otherwise, to any person or party not authorized under this Protective Order, then the Receiving Party shall use its best efforts to retrieve immediately all copies of the Designated Material, and to bind the person to the terms of this Protective Order. In that event, the Receiving Party shall also (i) promptly inform that person of all the provisions of this Protective Order; (ii) identify that person immediately to the Producing Party; and (iii) request that person to execute the Agreement to be Bound by Protective Order (Exhibit A) and confirm destruction or return of the material and all copies and derivations (including any notes or work product made therefrom).

21. Counsel's Right to Provide Advice

Nothing in this Protective Order shall bar or otherwise restrict any counsel herein from rendering advice to the counsel's Party-client with respect to these Actions, and in the course thereof, relying upon an examination of Designated Material, provided, however, that in rendering advice and in otherwise communicating with the Party-client, the counsel shall not disclose any Designated Material to anyone not authorized to receive Designated Material pursuant to the terms of this Protective Order.

22. No Contract

To the extent that the parties have agreed on the terms of this Protective Order, this stipulation is for the Court's consideration and approval as an order. The Parties' stipulation shall not be construed to create a contract between the Parties, or between the Parties and their respective counsel.

23. Effective Date

This Protective Order shall be effective on the date of its execution, provided that all material previously produced shall be deemed HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER unless and until they are re-designated by the Producing Party or by further order of the Court.

24. Termination

The termination of these Actions shall not automatically terminate the effectiveness of this Protective Order. Persons subject to this Protective Order shall be bound by the confidentiality obligations of this Protective Order until the Producing Party agrees otherwise in writing or this Court (or any other court or competent jurisdiction) orders otherwise.

SO ORDERED this _____ day of _____, 2022

_____

United States District Judge

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

draft

_____

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September 13, 2022

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	C.A. No. 21-1286 (LPS)
v.	)	C.A. No. 21-1455 (LPS)
	)	
BIONPHARMA INC.,	)	
	)	
Defendant.	)	

AGREEMENT TO BE BOUND BY PROTECTIVE ORDER

I, _____, state that:

1. My present employer is _____; and my work address is _____

_____.

2. My present occupation or job description is _____

_____.

3. My relationship to a Party/the Parties in the Action(s) is _____

_____.

4. I have carefully read and understood the provisions of the Protective Order in these Actions signed by the Court, and I will comply with and agree to be bound by all provisions of the Protective Order.

5. I will hold in confidence and not disclose to anyone not qualified under the Protective Order any Discovery Material designated HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER (*i.e.*, Designated Material) or any words, summaries, abstracts, or indices of such information disclosed to me.

6. I will only use Designated Material disclosed to me solely for the purposes of these Actions.

7. No later than the final conclusion of the last of these Actions, I will return, or certify complete destruction of, all Designated Material and summaries, abstracts, and indices thereof which come into my possession, and documents or things which I have prepared relating thereto, to outside counsel for the Party/Parties for whom I am/was employed or have been retained.

8. I agree to submit myself to the jurisdiction of the United States District Court for the District of Delaware, or other jurisdiction where these Actions may be pending, for the purpose of enforcing the terms of this undertaking.

9. I understand that if I violate the provisions of the Protective Order, I will be in violation of a Court order and subject to sanctions or other remedies that may be imposed by the Court and potentially liable in a civil action for damages.

10. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Date: _____ _____

[Signature]

_____

[Printed Name]

EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	C.A. No. 21-1286 (MSG)
v.	)	C.A. No. 21-1455 (MSG)
	)	
BIONPHARMA INC.,	)	
	)	
Defendant.	)	

[PROPOSED] STIPULATED PROTECTIVE ORDER

Plaintiff Azurity Pharmaceuticals, Inc. ("Plaintiff" or "Azurity"), and Defendant Bionpharma, Inc. ("Bionpharma") (Plaintiff and Defendant together, "Parties" and both individually, a "Party") assert that they possess confidential information in the form of trade secrets or other confidential business, commercial, personal, proprietary, and/or technical information related to the subject matter of Civil Action Nos. 21-1286 and 21-1455 (individually, an "Action" and collectively, "Actions"). These above-captioned Actions concern patent disputes relating to United States Patent Nos. 11,040,023 ("'023 Patent") and 11,141,405 ("'405 Patent") (collectively, "Patents-in-Suit"). The Parties recognize that it may be necessary to disclose certain confidential information during the course of these Actions, and contemplate that non-parties may produce confidential information. Pursuant to Federal Rules of Civil Procedure ("Fed. R. Civ. P.") 26(c), and for good cause shown, the Parties, by and through their respective undersigned counsel, hereby stipulate and consent to the entry of this Stipulated Protective Order ("Protective Order").

1. Definitions and Scope

(a) "Discovery Material" means any document, material, item, testimony, or thing filed with or presented to the Court or produced, served, or generated during the discovery process, including but not limited to exhibits, answers to interrogatories, responses to requests for

admissions, responses to requests for production, subpoenas, declarations, affidavits, deposition testimony or transcripts, and all copies, extracts, summaries, compilations, designations, and portions thereof.

(b) Discovery Material designated as "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER" by a Producing Party means such Discovery Material comprises or contains highly sensitive and/or proprietary technical, commercial, financial, or business information including without limitation:

(i) trade secrets, ownership, management, corporate structure or organization, business and/or strategic plans, financial planning or performance, budgeting, advertising expenditures, accounting, decisions and/or processes, license agreements, negotiations, sales projections, profit projections, market share projections, pricing plans and pricing analysis, non-public sales data and analysis, non-public market share data, and non-public documents, materials, or information relating to present or prospective customers, dealers, and distributors (such as proposals, bids or contracts), current or future, the disclosure of which could result in severe competitive or commercial disadvantage to the Producing Party;

(ii) as purporting to cover enalapril maleate oral solutions: non-public patent applications and files; non-public research, development, formulation, manufacture, testing, or evaluation of pharmaceuticals; approved or unapproved (whether pending or not yet filed) New Drug Applications ("NDA") or Abbreviated New Drug Applications ("ANDA"); non-public

communications with the United States Food and Drug Administration ("FDA");

(iii) information received under confidentiality restrictions or an agreement from vendors, suppliers, and/or third parties;

(iv) private or confidential personal information, patient information, or personal health information including information protected under the Health Insurance Portability and Accountability Act of 1996;

(v) drafts, attachments, or internal communications related to the foregoing.

HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER Discovery Material may be disclosed only to the individuals identified in Paragraph 5 below.

(c) "Designated Material" means any Discovery Material designated by a Producing Party as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER. Each Party shall act reasonably and in good faith in designating Discovery Material as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER.

(d) "Producing Party" means any Party to the Actions or any non-party, including its counsel, retained experts and consultants, third party testing laboratories, directors, officers, employees, or agents, who produces any Discovery Material in the Actions.

(e) "Receiving Party" means any Party to the Actions, including its counsel, retained experts and consultants, third party testing laboratories, directors, officers, employees, or agents, who receives any Discovery Material in the Actions.

(f) This Protective Order encompasses not only Discovery Material that is expressly designated HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER, but also any information derived therefrom, including all copies, excerpts, and summaries thereof, whether

partial or complete, as well as testimony and oral conversations that reveal all or part of such information, and any other discovery taken or disclosures provided pursuant to the Federal Rules of Civil Procedure or District of Delaware Local Rules.

2. Procedure for Marking and Designating Discovery Material

Marking Discovery Material as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER shall be made by the Producing Party in the following manner:

(a) In the case of documents or any other tangible thing produced, designation shall be made by placing the legend "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER" on each page of the document, or on the cover, or in a prominent place on any other tangible thing prior to production of the document or tangible thing.

(b) In producing original files and records for inspection, no marking need be made by the Producing Party in advance of the inspection. For the purposes of the inspection, all documents produced for inspection shall initially be considered as marked "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER." Thereafter, upon selection of specified documents for copying by the Receiving Party, the Producing Party shall mark such Designated Material as "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER" based on the definitions discussed in Paragraph 1(b).

(c) In the case of deposition testimony, transcripts, or portions thereof, designation shall be made by the Producing Party as follows:

(i) on the record during the deposition, in which case the portion of the transcript of the designated testimony shall be bound in a separate volume and marked "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER" by the reporter;

(ii) by written notice to the reporter and all counsel of record, given within thirty (30) calendar days after the reporter sends written notice to the deponent or the deponent's counsel that the transcript is available for review, in which case all counsel receiving the notice shall be responsible for marking the copies of the designated transcript or portion(s) thereof in their possession or control as directed by the Producing Party or deponent; or

(iii) by written notice to the reporter and all counsel of record, given within thirty (30) calendar days after reporter sends written notice to the deponent or the deponent's counsel that the transcript is available for review, that certain portions can be re-designated as not confidential. Pending expiration of the thirty (30) calendar days, all Parties and, if applicable, any third-party witnesses or attorneys, shall treat the deposition transcript as if it had been designated "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER."

No person shall attend the portions of depositions designated HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER unless that person is an authorized recipient of material designated HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER pursuant to the terms of this Protective Order or the Parties agree to that person's attendance.

3. Challenging Designations

(a) No Party to these Actions shall be obligated to challenge the propriety of any designation by any Producing Party, and a failure to do so shall not constitute a waiver or in any way preclude a later challenge to the propriety of the designation in these Actions.

(b) Any Party may contest a claim of confidentiality. Any Party objecting to the designation of any Discovery Material as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER must serve outside counsel of record for the Producing Party written notice of its reasons, described with particularity, for the objection, and identify the information, preferably by production number. Counsel for the Producing Party shall respond in writing to such objection within five (5) business days[1] and shall state with particularity the grounds for asserting that the Discovery Material is HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER.

(c) Failing resolution after ten (10) business days from service of the objecting Party's written notice of reasons for objection, the objecting Party may seek an order changing or removing the designation. In resolving the matter, the burden of establishing confidentiality shall be on the Party who made the claim of confidentiality, *i.e.*, the Producing Party, but information designated as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER shall be deemed so designated until the matter is resolved.

4. Restrictions on Disclosure and Use

(a) CONFIDENTIALITY

Designated Material and the information derived from the Designated Material (excluding information which is derived lawfully from an independent source) shall not be given, shown, made available, discussed, or otherwise communicated in any manner, to any person not authorized to receive the information pursuant to the terms of this Protective Order, unless and to the extent that this Protective Order is otherwise modified by court order. Any summary,

[1] A "business day" is a day on which the Clerk's Office of the United States District Court for the District of Delaware is open.

compilation, notes, memoranda, analysis, electronic image, or database containing Designated Material shall be subject to the terms of this Protective Order to the same extent as the material or information from which the summary, compilation, notes, memoranda, analysis, electronic image, or database is derived.

(b) RESTRICTIONS ON USE

Absent an agreement of the Producing Party or an order to the contrary by this Court, each Party and all other persons bound by the terms of this Protective Order shall use any material designated as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER solely for purposes of these Actions and any appeal therefrom. Such Designated Material shall not be used for any other purpose, including, without limitation, any business, commercial, competitive, personal, or other purpose.

Specifically, HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER material obtained from these Actions shall not be submitted, used, or relied upon to prepare submissions to the U.S. Food and Drug Administration ("FDA") or U.S. Patent and Trademark Office ("USPTO"). Counsel of record for the parties shall exercise reasonable care to ensure that the information and documents governed by this Protective Order are (i) used only for the purpose specified herein, and (ii) disclosed only to authorized persons.

Absent consent of the Producing Party or further order of this Court, all outside counsel of record as defined in Paragraph 5(a) ~~and designated in-house representatives as defined in Paragraph 5(k)~~ who are substantively involved in the drafting or prosecution of claims in patents and/or patent applications relating to the Patents-in-Suit (including any continuations, continuations-in-part, or divisionals thereof claiming enalapril maleate oral solutions, or processes for making enalapril maleate oral solutions, or methods of treatment involving enalapril maleate

oral solutions) will not have access to any documents containing the formulation for Bionpharma's product produced pursuant to ANDA No. 212408 ("Bionpharma Formulation Material"). For avoidance of doubt, the Bionpharma Formulation Material is information that discloses the entirety of Bionpharma's qualitative formulation, or the amount or concentration of any excipient contained in Bionpharma's ANDA product.~~are excluded from access to information designated HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER~~. For the avoidance of doubt, being "substantively involved in the drafting or prosecution of claims in patents and/or patent applications" in the previous sentence shall mean the drafting or amending of claims, or providing direction or input on the drafting or amending of claims. Outside counsel of record as defined in Paragraph 5(a) ~~and designated in-house representatives as defined in Paragraph 5(k)~~ who do have access to ~~information designated HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER~~Bionpharma Formulation Material cannot participate in such aforementioned activities during the pendency of these Actions, including any appeals therefrom, and for twelve (12) months after the last of these Actions is finally terminated.

For clarity, nothing in this agreement prohibits persons with access to HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER information from participating in opposition, reexamination, *inter partes* review, or other post-grant proceedings (except reissue) before the USPTO or before any foreign patent-granting authority (collectively, "Post-Grant Proceedings"). However, no outside counsel of record as defined in Paragraph 5(a) ~~or designated in-house representatives as defined in Paragraph 5(k)~~ who do have access to Bionpharma Formulation Material~~information designated HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER~~ shall draft or provide any input on the drafting and/or amendment of claims in any Post-Grant Proceeding pertaining to enalapril maleate oral solutions during the

pendency of these Actions, including any appeals therefrom, and for twelve (12) months after these Actions are terminated, but such outside counsel of record as defined in Paragraph 5(a) and in-house representatives may otherwise fully participate in all such Post-Grant Proceedings pertaining to enalapril maleate oral solutions.

For the avoidance of doubt, outside counsel who do not have access to Bionpharma Formulation Material ~~information designated HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER~~ under this Protective Order ~~and in-house representatives other than those defined in Paragraph 5(k)~~ are not restricted in any manner by this Paragraph 4(b), and for example, may therefore freely draft, amend, and/or prosecute claims before the USPTO or before any foreign patent-granting authority. For the further avoidance of doubt, outside counsel who do not have "access" to Designated Material under this Protective Order means that such persons have not received Designated Material and will not attempt to obtain or view such Designated Material within the outside counsel firm's servers or other storage locations. All outside counsel of record in these Actions are presumed to have "access" to Designated Material as that term is used in this Paragraph and are subject to the restrictions of this Paragraph 4(b).

(c) MAINTENANCE OF DESIGNATED MATERIAL

Designated Material shall be maintained by the Receiving Party at a location and under circumstances to ensure that access is limited to only those persons entitled to have access pursuant to this Protective Order.

A Producing Party is free to do whatever it desires with its own Designated Material.

5. Access to Designated Material

Designated Material shall be available only to the following persons subject to the terms of Paragraph 6:

(a) Outside counsel of record to any Party in connection with these Actions, and the outside counsel's partners, associates, attorneys, data entry, information processing, computer support, artist, translating, stenographic, clerical, and paralegal employees or agents whose duties and responsibilities require and who actually have access to materials designated "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER," subject to the restrictions set forth in Paragraph 4(b).

(b) The Court, including Judges, Magistrate Judges, law clerks, and clerical personnel of the Court before which these Actions are pending, and qualified court reporters;

(c) Approved consultants or experts and their staff, but excluding employees, officers, or directors of a named Party, retained by any of the Parties or their counsel to consult or testify in these Actions subject to the terms of Paragraph 6(a);

(d) Authors or drafters; addressees; anyone else who received the documents or information prior to the commencement of these Actions, or during these Actions, but only if they obtained the document or information outside of these Actions and not in violation of this Protective Order; provided that, in the case of former employees/consultants of the Producing Party permitted access pursuant to this provision, (i) the former employee/consultant reviews this Protective Order and executes the Agreement to be Bound by Protective Order, in the form shown in Exhibit A, which is attached hereto, prior to receiving Designated Material, (ii) the former employee/consultant of the Producing Party is not employed or retained by the Receiving Party, and (iii) Designated Material is shared with the former employee/consultant of the Producing Party only during a deposition taken in these Actions.

(e) Third party contractors and their employees involved in document management or copying services for these Actions;

(f) Graphics or design services retained by counsel for a Party for purposes of preparing demonstratives or other exhibits for deposition, trial, or other court proceedings in these Actions;

(g) Trial consulting services retained by a Party in these Actions;

(h) Persons who have been retained by a Party to provide translation or interpretation from one language to another;

(i) Third party testing laboratories and their staffs retained by any of the parties or their counsel for purposes of these Actions subject to the terms of Paragraph 6(b); and

(j) Any other person authorized to receive HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER Designated Material by order of the Court or by written agreement of the parties;

(k) Two (2) designated in-house representatives for each Party who have responsibility for maintaining and/or overseeing these Actions, as well as their secretarial and clerical staff. Such representatives must execute a copy of the Agreement to be Bound by Protective Order (Exhibit A) prior to being given access to material designated as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER.

~~(k)~~ ~~Notwithstanding the patent prosecution and FDA practice restrictions of Paragraph 4(b),~~ Azurity~~'s may designate Mr. Hanok George as an~~ in-house representative~~s as indicated in paragraph 5(k) are~~ permitted to receive Designated Material produced by Bionpharma (~~provided Mr. George executes~~upon execution of a copy of the Agreement to be Bound by Protective Order (Exhibit A)), and ~~Mr. George~~ will be permitted access to Designated Material produced by Bionpharma pursuant to the restrictions contained in this Order. However, ~~Mr.~~

~~George~~Azurity's in-house counsel will not have access to any documents containing ~~the formulation for Bionpharma's product produced pursuant to ANDA No. 212408 (~~"Bionpharma Formulation Material"~~)~~. ~~For avoidance of doubt, the Bionpharma Formulation Material is information that discloses the entirety of Bionpharma's qualitative formulation, or the amount or concentration of any excipient contained in Bionpharma's ANDA product.~~ All Bionpharma Formulation Material will be redacted in any document prepared for purposes of this litigation prior to sending to ~~Mr. George~~the in-house representatives indicated in paragraph 5(k).

(l)

6. Conditions on Access to Designated Material

(a) CONSULTANTS AND EXPERTS

Prior to a Receiving Party giving, showing, disclosing, making available, or communicating Designated Material to any expert or consultant under Paragraph 5(c), the Receiving Party shall:

(i) Provide written notice to the Producing Party identifying the expert or consultant and the following information:

(A) The expert's or consultant's business address, present employer and position (including a job description), and job history;

(B) a list of prior consulting relationships for companies involved in the development, manufacturing, marketing or sale of pharmaceutical products for the past five (5) years;

(C) the case name, number, and location of the court for any litigation in connection with which the expert or consultant has offered expert

testimony, including through a declaration, report, or testimony at a deposition or trial, during the preceding five (5) years; and

(D) past or present relationship, if any, with the Receiving Party and/or Producing Party.

(E) Furthermore, the most recent curriculum vitae or resume of the expert or consultant shall be provided pursuant to this section. If the most recent curriculum vitae or resume of the expert or consultant provides the information required pursuant to this Paragraph, then the information need not be separately provided.

(ii) Include with the notice, a copy of Agreement to be Bound by Protective Order (Exhibit A), signed by the expert or consultant.

(iii) The Producing Party shall be entitled to object to any disclosure of Designated Material to the expert or consultant within five (5) business days after receipt of the Agreement to be Bound by Protective Order by stating specifically in writing the reasons why the identified expert or consultant should not receive the Designated Material. Proper objectionable grounds include but are not limited to:

(A) The proposed expert or consultant is currently employed or anticipates future employment by Plaintiff or Defendant(s);

(B) The proposed expert or consultant is performing work-related to any product that is the subject of the Patents-in-Suit separate and apart from the work performed in connection with these Actions;

(C) The proposed expert or consultant is performing work related to any pharmaceutical drug product designed to directly compete with the products involved in these Actions.

(iv) If the Parties are unable to agree on disclosure of Designated Material to the expert or consultant, the objecting Party may apply to the Court for an order that disclosure is improper within ten (10) calendar days of its objection. The burden of establishing the validity of written objections rests with the objecting Party. If the objecting Party does not apply to the Court within the prescribed period, the objection shall be deemed withdrawn by using the procedure set forth in Paragraph 7(h) of the Scheduling Order (No. 21-1286, D.I. 126).

(v) No disclosure of the Designated Material shall be made to the proposed expert or consultant until the time for serving objections to that expert or consultant has passed, or, in the event that a written objection is timely served and a submission to prevent disclosure is filed, until the Court has made a ruling thereon, and then, only in accordance with that ruling.

(vi) The filing and pendency of objections shall not limit, delay, or defer any disclosures of Designated Material to the expert or consultant as to whom no objection has been made, nor shall it delay or defer any other pending discovery unless the level of confidentiality bears directly on the objecting Party's ability to conduct that discovery.

(b) THIRD PARTY TESTING LABORATORIES

Counsel may use the services of third party testing laboratories to perform tests and analyses for the Actions on Designated Material marked HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER. Prior to a Receiving Party giving, showing, disclosing, making available, or communicating Designated Material to any third party testing laboratory pursuant to Paragraph 5(i) above, the Receiving Party shall:

(i) Provide written notice to the Producing Party, identifying the third party testing laboratory, the third party testing laboratory's business address, and past or present relationship, if any, the third party testing laboratory has/had with the Receiving Party and/or Producing Party.

(ii) Include with the notice a copy of the Agreement to be Bound by Protective Order (Exhibit A), signed by a representative of the third party testing laboratory.

(iii) The Producing Party shall be entitled to object to the disclosure of Designated Material to the third party testing laboratory within ten (10) calendar days after receipt of the Acknowledgment of Protective Order by stating specifically in writing the reasons why the third party testing laboratory should not receive the Designated Material.

(iv) If the parties are unable to agree on the disclosure to the third party testing laboratory, the objecting Party may apply to the Court for an order that disclosure of Designated Material is improper within ten (10) calendar days of its objection. The burden of establishing the validity of written objections rests with the objecting Party. If the objecting Party does not apply to the Court within the prescribed period, the objection shall be deemed

withdrawn by using the procedure set forth in Paragraph 7(h) of the Scheduling Order (No. 21-1286, D.I. 126).

(v) No disclosure of the Designated Material shall be made to the proposed third party testing laboratory until the time for serving objections to that third party testing laboratory has passed, or, in the event that a written objection is timely served and a submission to prevent disclosure is filed, until the Court has made a ruling thereon, and then, only in accordance with that ruling.

(vi) The filing and pendency of objections shall not limit, delay, or defer any disclosures of Designated Material to third party testing laboratories as to whom no objection has been made, nor shall it delay or defer any other pending discovery unless the level of confidentiality bears directly on the objecting Party's ability to conduct that discovery.

~~for purposes of this litigation prior to sending to Azurity in-house representatives.~~

(c) AUTHORIZATION AND ACKNOWLEDGEMENT

Persons or firms retained by Plaintiff or Defendant(s) to whom Designated Material is to be given, shown, disclosed, made available, or communicated in any way in accordance with this Protective Order (excluding the Court, *e.g.*, Judges, Magistrate Judges, law clerks, qualified court reporters, and clerical personnel of the Court before which these Actions are pending; and outside counsel of record to any Party in connection with these Actions and the outside counsel's partners, associates, attorneys, data entry, information processing, computer support, artist, translating, stenographic, clerical, and paralegal employees or agents whose duties and responsibilities require access to materials designated HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE

ORDER), shall first execute an Agreement to be Bound by Protective Order (Exhibit A). Counsel for the Receiving Party shall keep in his or her files an original of each executed Acknowledgment of Protective Order until sixty (60) calendar days after the final termination of these Actions.

7. Procedures for Filing Papers with Designated Material

Designated Material may be included with, or referred to in, papers filed with the Court where these Actions are now pending or in any other court only in accordance with the following procedures:

(a) The Designated Material must be filed under seal in accordance with the applicable procedures set forth in the Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware and any Orders of the Court.

(b) All papers filed with the Court, including but not limited to pleadings and memoranda of law, which include all or any portion of information set forth in Designated Material must be filed under seal in accordance with the terms and procedures set forth in this Order, including the procedures for filing materials set forth above in Paragraph 7(a). Counsel for the Party filing papers with Designated Material shall be responsible for designating all papers filed with the Court as Designated Material and marked as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER depending on the contents of the papers being filed. The papers shall be subject to the terms of this Order.

8. Redacted Filings of Papers with Designated Material

Redacted versions of papers with Designated Materials filed under seal must be filed with the Court in accordance with the applicable procedures set forth in the Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware and any orders of the Court, and made publicly available provided that:

(a) All Designated Material set forth in the papers is deleted or obscured and all Designated Material is removed as exhibits; and

(b) Redacted versions of the papers are clearly marked "REDACTED PUBLIC VERSION" or a similar legend. Redacted versions of the papers also must clearly identify each place where information or exhibits have been deleted.

9. Unintentional Failure to Designate and Inadvertent Production

If, through inadvertence, regardless of reason or circumstances, a Producing Party provides any Designated Material in these Actions without designating and marking the Designated Material as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER, the Producing Party may subsequently inform the Receiving Party of the confidential nature of the disclosed Designated Material. The Receiving Party shall treat the disclosed Designated Material as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER upon receipt of written notice from the Producing Party, to the extent the Receiving Party has not disclosed this Designated Material to persons not authorized to receive that material under Paragraph 5.

Disclosure of Designated Material to persons not authorized to receive that material prior to receipt of the confidentiality designation shall not be deemed a violation of this Protective Order. However, in the event the material has been distributed in a manner inconsistent with the categorical designation, the Receiving Party promptly will take the steps reasonably necessary to (i) conform distribution to the categorical designation, *i.e.*, by retrieval and destruction of all copies of the Designated Material, or notes or extracts thereof, in the possession of the person(s) not authorized under this Protective Order to possess the Designated Material; (ii) advise the person(s) to whom disclosure was made that the material is confidential and should be treated as provided in the Protective Order, and (iii) confirm to the Producing Party in writing the retrieval or

destruction. In the event the Receiving Party believes it has been prejudiced by any inadvertent failure to designate, the Receiving Party may contest the designation as set forth in Paragraph 3.

10. Privileged Information

The Parties agree that, as to objections based on attorney-client privilege, work product, or other immunity from discovery pursuant to Fed. R. Civ. P. 26 and Federal Rule of Evidence ("F.R.E.") 502, in response to requests for production pursuant to Fed. R. Civ. P. 34 and interrogatories pursuant to Fed. R. Civ. P. 33, to the extent that a Party is required at the time of making such objection to provide information identifying documents or information withheld from production because of objections based on privilege or immunity, the information shall be provided in the form of a privilege log at a mutually agreed upon time on or before the close of fact discovery. The Parties agree that production of a privilege log at the mutually agreed upon time shall not constitute waiver of the asserted privilege or immunity as to any document or information.

Counsel shall exert their best efforts to identify documents or material protected by the attorney-client privilege, the attorney work-product doctrine, the common-interest doctrine, or any other privilege or immunity prior to the disclosure of any documents or material. If, however, a Party unintentionally regardless of reason or circumstances, discloses documents or material that is privileged or otherwise immune from discovery, the Party shall, promptly upon discovery of the disclosure, so advise the Receiving Party in writing, request the documents or material be returned or destroyed, and attach a privilege log entry within twenty (20) calendar days pertaining to the documents or material that is privileged or otherwise immune from discovery. If that request is made and the privilege log provided, no Party to the Actions shall thereafter assert that the disclosure waived any privilege or immunity.

It is further agreed that the Receiving Party will return or destroy the inadvertently produced documents or material, and all copies and derivations (including any notes or work product made therefrom), within five (5) business days of the Receiving Party's receipt of a written request for the return of the documents or material. The Receiving Party having returned or destroyed the inadvertently produced documents or material may thereafter seek production of the documents or material in accordance with the Federal Rules of Civil Procedure, but cannot assert that the privilege has been waived due to the unintentional disclosure. These procedures are not intended to in any way limit the right of a Party to argue pursuant to F.R.E. 502 or any other law that any inadvertent production did not constitute a waiver, except that the Receiving Party shall not sequester or retain the inadvertently produced documents in any manner or for any purpose, including for purposes of challenging the privilege claim.

In the event that a Receiving Party, in good faith, believes that the document(s) or tangible item(s) that were withdrawn by the Party claiming privilege are not properly subject to a claim of attorney-client privilege, work product immunity, or any other privilege or immunity, the Receiving Party may only use the privilege log as the basis for any motion to compel, and not the contested document. For the avoidance of doubt, the Court (including Judges, Magistrate Judges, law clerks, and clerical personnel of the Court before which these Actions are pending) is permitted to review the contested document in-camera in conjunction with a motion to compel.

11. Information Not Covered by Protective Order

The restrictions set forth in this Protective Order shall not apply to information which is in the possession of or otherwise known to the Receiving Party or the public before the date of its transmission to the Receiving Party, or which lawfully comes into the possession of or becomes known to the Receiving Party or lawfully comes into the possession of or otherwise becomes

known to the public after the date of its transmission to the Receiving Party, provided that the information does not become publicly known by any act or omission of the Receiving Party which would be in violation of this Protective Order.

12. Responsibility of Attorneys

Outside counsel of record shall be responsible for providing a copy of this Protective Order to all persons entitled access to Designated Material under Paragraph 5 and to employ reasonable measures to control duplication of, access to, and distribution of copies of materials so designated. All copies, extracts and translations must be appropriately marked and are subject to Paragraph 13 of this Protective Order.

13. Final Disposition

Upon termination, settlement, or final judgment of these Actions, including exhaustion of all appeals, the originals and all copies of Designated Material shall be either destroyed or turned over to the Producing Party, or to their respective outside counsel, within ninety (90) calendar days. However, outside counsel may retain court filings and other pleadings and discovery served; trial, deposition, and hearing transcripts; correspondence; expert reports; attorney and consultant work product; and deposition and trial exhibits for archival purposes. If Designated Material is destroyed pursuant to this Paragraph, outside counsel for the Receiving Party shall provide to outside counsel for the Producing Party a certification that the destruction was performed. The provisions of this Protective Order insofar as it restricts the disclosure, communication of, and use of Designated Material produced hereunder shall continue to be binding after the conclusion of these Actions.

14. No Limitation on Other Rights

This Protective Order shall be without prejudice to the right of any Party to oppose production of any information on any and all grounds other than confidentiality.

15. Release from or Modification of Protective Order

This Protective Order is entered without prejudice to the right of any Party to apply to the Court at any time for additional protection; or to release, rescind, or modify the restrictions of this Protective Order; to determine whether a particular person shall be entitled to receive any particular information; or to seek relief from inadvertent disclosure of privileged or work-product information. This Protective Order does not preclude all of the parties to this Protective Order from entering into any stipulation (in writing or on the record) constituting a modification of this Protective Order. On any application seeking disclosures beyond those authorized by this Protective Order, the burden will be on the Receiving Party to justify the disclosure.

16. Other Proceedings

By entering this Protective Order and limiting the disclosure of information in these Actions, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or Party subject to this Protective Order who becomes subject to a motion to disclose another Party's information designated HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER pursuant to this Protective Order in another case shall promptly notify that other Party of the motion so that the other Party may have an opportunity to appear and be heard on whether that information should be disclosed.

17. Discovery from Third Parties

If discovery is sought of a person not a Party to these Actions (*i.e.*, a third party) requiring disclosure of said third party's Designated Material, the Designated Material disclosed by the third

party will be accorded the same protection as the parties' Designated Material, and will be subject to the same procedures as those governing disclosure of the parties' Designated Material pursuant to this Protective Order. Should a Party to these Actions have a good faith basis that the third party production may contain a Party's confidential information, that Party shall be allowed to designate that information according to this Protective Order within twenty-one (21) calendar days of receipt of that production.

18. Admissibility

Nothing herein shall be construed to affect in any way the evidentiary admissibility of any document, testimony, or other matter at any court proceeding related to the Action. The marking of Designated Material as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER pursuant to this Protective Order shall not, for that reason alone, bar its introduction or use at any court proceeding related to these Actions pursuant to the terms and conditions as the Court may deem appropriate, consistent with the need for a complete and accurate record of the proceedings, provided, however, that every effort shall be made, through the use of procedures agreed upon by the Parties or otherwise, to preserve the confidentiality of Designated Material.

19. Non-Party Request and/or Subpoena of Designated Material

If a Receiving Party receives a subpoena or other compulsory process from a non-party to this Protective Order seeking production or other disclosure of a Producing Party's Designated Material, that Receiving Party shall give written notice to outside counsel of record for the Producing Party within five (5) business days after receipt of the subpoena or other compulsory process identifying the specific Designated Material sought and enclosing a copy of the subpoena or other compulsory process. If the Producing Party timely seeks a protective order, the Receiving Party to whom the subpoena or other compulsory process was issued or served shall not produce

the Designated Material requested prior to receiving a court order or consent of the Producing Party. In the event that Designated Material is produced to the non-party, the material shall be treated as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER pursuant to this Protective Order.

20. Unintentional Disclosure of Designated Material

If Designated Material, or any portion thereof, is disclosed by the Receiving Party, through inadvertence or otherwise, to any person or party not authorized under this Protective Order, then the Receiving Party shall use its best efforts to retrieve immediately all copies of the Designated Material, and to bind the person to the terms of this Protective Order. In that event, the Receiving Party shall also (i) promptly inform that person of all the provisions of this Protective Order; (ii) identify that person immediately to the Producing Party; and (iii) request that person to execute the Agreement to be Bound by Protective Order (Exhibit A) and confirm destruction or return of the material and all copies and derivations (including any notes or work product made therefrom).

21. Counsel's Right to Provide Advice

Nothing in this Protective Order shall bar or otherwise restrict any counsel herein from rendering advice to the counsel's Party-client with respect to these Actions, and in the course thereof, relying upon an examination of Designated Material, provided, however, that in rendering advice and in otherwise communicating with the Party-client, the counsel shall not disclose any Designated Material to anyone not authorized to receive Designated Material pursuant to the terms of this Protective Order.

22. No Contract

To the extent that the parties have agreed on the terms of this Protective Order, this stipulation is for the Court's consideration and approval as an order. The Parties' stipulation shall

not be construed to create a contract between the Parties, or between the Parties and their respective counsel.

23. Effective Date

This Protective Order shall be effective on the date of its execution, provided that all material previously produced shall be deemed HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER unless and until they are re-designated by the Producing Party or by further order of the Court.

24. Termination

The termination of these Actions shall not automatically terminate the effectiveness of this Protective Order. Persons subject to this Protective Order shall be bound by the confidentiality obligations of this Protective Order until the Producing Party agrees otherwise in writing or this Court (or any other court or competent jurisdiction) orders otherwise.

SO ORDERED this _____ day of _____, 2022

_____

United States District Judge

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

draft

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September 13, 2022~~September 12, 2022August 29, 2022August 29, 2022July 25, 2022July 22, 2022~~

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	C.A. No. 21-1286 (LPS)
v.	)	C.A. No. 21-1455 (LPS)
	)	
BIONPHARMA INC.,	)	
	)	
Defendant.	)	

AGREEMENT TO BE BOUND BY PROTECTIVE ORDER

I, _____, state that:

1. My present employer is _____; and my work address is _____

_____.

2. My present occupation or job description is _____

_____.

3. My relationship to a Party/the Parties in the Action(s) is _____

_____.

4. I have carefully read and understood the provisions of the Protective Order in these Actions signed by the Court, and I will comply with and agree to be bound by all provisions of the Protective Order.

5. I will hold in confidence and not disclose to anyone not qualified under the Protective Order any Discovery Material designated HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER (*i.e.*, Designated Material) or any words, summaries, abstracts, or indices of such information disclosed to me.

6. I will only use Designated Material disclosed to me solely for the purposes of these Actions.

7. No later than the final conclusion of the last of these Actions, I will return, or certify complete destruction of, all Designated Material and summaries, abstracts, and indices thereof which come into my possession, and documents or things which I have prepared relating thereto, to outside counsel for the Party/Parties for whom I am/was employed or have been retained.

8. I agree to submit myself to the jurisdiction of the United States District Court for the District of Delaware, or other jurisdiction where these Actions may be pending, for the purpose of enforcing the terms of this undertaking.

9. I understand that if I violate the provisions of the Protective Order, I will be in violation of a Court order and subject to sanctions or other remedies that may be imposed by the Court and potentially liable in a civil action for damages.

10. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Date: _____ _____

[Signature]

_____

[Printed Name]

EXHIBIT 3

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	C.A. No. 21-1286- (MSG)
v.	)	C.A. No. 21-1455- (MSG)
	)	
BIONPHARMA INC.,	)	
	)	
Defendant.	)	

[PROPOSED] STIPULATED PROTECTIVE ORDER

Plaintiff Azurity Pharmaceuticals, Inc. ("Plaintiff" or "Azurity"), and Defendant Bionpharma, Inc. (~~"Defendant" or~~ "Bionpharma") (Plaintiff and ~~Bionpharma~~ Defendant together, "Parties" and ~~each~~both individually, a "Party") assert that they possess confidential information in the form of trade secrets or other confidential business, commercial, personal, proprietary, and/or technical information related to the subject matter of Civil Action Nos. 21-1286 and 21-1455 (individually, an "Action" and collectively, "Actions"). These above-captioned Actions concern patent disputes relating to United States Patent Nos. 11,040,023 ("'023 Patent") and 11,141,405 ("'405 Patent") (collectively, "Patents-in-Suit"). The Parties recognize that it may be necessary to disclose certain confidential information during the course of these Actions, and contemplate that non-parties may produce confidential information. Pursuant to Federal Rules of Civil Procedure ("Fed. R. Civ. P.") 26(c), and for good cause shown, the Parties, by and through their respective undersigned counsel, hereby stipulate and consent to the entry of this Stipulated Protective Order ("Protective Order").

1. Definitions and Scope

(a) "Discovery Material" means any document, material, item, testimony, or thing filed with or presented to the Court or produced, served, or generated during the discovery process,

including but not limited to exhibits, answers to interrogatories, responses to requests for admissions, responses to requests for production, subpoenas, declarations, affidavits, deposition testimony or transcripts, and all copies, extracts, summaries, compilations, designations, and portions thereof.

(b) Discovery Material designated as "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER" by a Producing Party means such Discovery Material comprises or contains highly sensitive and/or proprietary technical, commercial, financial, or business information including without limitation:

(i) trade secrets, ownership, management, corporate structure or organization, business and/or strategic plans, financial planning or performance, budgeting, advertising expenditures, accounting, decisions and/or processes, license agreements, negotiations, sales projections, profit projections, market share projections, pricing plans and pricing analysis, non-public sales data and analysis, non-public market share data, and non-public documents, materials, or information relating to present or prospective customers, dealers, and distributors (such as proposals, bids or contracts), current or future, the disclosure of which could result in severe competitive or commercial disadvantage to the Producing Party;

(ii) as purporting to cover enalapril maleate oral solutions: non-public patent applications and files; non-public research, development, formulation, manufacture, testing, or evaluation of pharmaceuticals; approved or unapproved (whether pending or not yet filed) New Drug Applications ("NDA") or Abbreviated New Drug Applications ("ANDA"); non-public

communications with the United States Food and Drug Administration ("FDA");

(iii) information received under confidentiality restrictions or an agreement from vendors, suppliers, and/or third parties;

(iv) private or confidential personal information, patient information, or personal health information including information protected under the Health Insurance Portability and Accountability Act of 1996;

(v) drafts, attachments, or internal communications related to the foregoing.

HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER Discovery Material may be disclosed only to the individuals identified in Paragraph 5 below.

(c) "Designated Material" means any Discovery Material designated by a Producing Party as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER. Each Party shall act reasonably and in good faith in designating Discovery Material as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER.

(d) "Producing Party" means any Party to the Actions or any non-party, including its counsel, retained experts and consultants, third party testing laboratories, directors, officers, employees, or agents, who produces any Discovery Material in the Actions.

(e) "Receiving Party" means any Party to the Actions, including its counsel, retained experts and consultants, third party testing laboratories, directors, officers, employees, or agents, who receives any Discovery Material in the Actions.

(f) This Protective Order encompasses not only Discovery Material that is expressly designated HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER, but also any information derived therefrom, including all copies, excerpts, and summaries thereof, whether

partial or complete, as well as testimony and oral conversations that reveal all or part of such information, and any other discovery taken or disclosures provided pursuant to the Federal Rules of Civil Procedure or District of Delaware Local Rules.

2. Procedure for Marking and Designating Discovery Material

Marking Discovery Material as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER shall be made by the Producing Party in the following manner:

(a) In the case of documents or any other tangible thing produced, designation shall be made by placing the legend "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER" on each page of the document, or on the cover, or in a prominent place on any other tangible thing prior to production of the document or tangible thing.

(b) In producing original files and records for inspection, no marking need be made by the Producing Party in advance of the inspection. For the purposes of the inspection, all documents produced for inspection shall initially be considered as marked "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER." Thereafter, upon selection of specified documents for copying by the Receiving Party, the Producing Party shall mark such Designated Material as "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER" based on the definitions discussed in Paragraph 1(b).

(c) In the case of deposition testimony, transcripts, or portions thereof, designation shall be made by the Producing Party as follows:

(i) on the record during the deposition, in which case the portion of the transcript of the designated testimony shall be bound in a separate volume and marked "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER" by the reporter;

(ii) by written notice to the reporter and all counsel of record, given within thirty (30) calendar days after the reporter sends written notice to the deponent or the deponent's counsel that the transcript is available for review, in which case all counsel receiving the notice shall be responsible for marking the copies of the designated transcript or portion(s) thereof in their possession or control as directed by the Producing Party or deponent; or

(iii) by written notice to the reporter and all counsel of record, given within thirty (30) calendar days after reporter sends written notice to the deponent or the deponent's counsel that the transcript is available for review, that certain portions can be re-designated as not confidential. Pending expiration of the thirty (30) calendar days, all Parties and, if applicable, any third-party witnesses or attorneys, shall treat the deposition transcript as if it had been designated "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER."

No person shall attend the portions of depositions designated HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER unless that person is an authorized recipient of material designated HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER pursuant to the terms of this Protective Order or the Parties agree to that person's attendance.

3. Challenging Designations

(a) No Party to these Actions shall be obligated to challenge the propriety of any designation by any Producing Party, and a failure to do so shall not constitute a waiver or in any way preclude a later challenge to the propriety of the designation in these Actions.

(b) Any Party may contest a claim of confidentiality. Any Party objecting to the designation of any Discovery Material as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER must serve outside counsel of record for the Producing Party written notice of its reasons, described with particularity, for the objection, and identify the information, preferably by production number. Counsel for the Producing Party shall respond in writing to such objection within five (5) business days[1] and shall state with particularity the grounds for asserting that the Discovery Material is HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER.

(c) Failing resolution after ten (10) business days from service of the objecting Party's written notice of reasons for objection, the objecting Party may seek an order changing or removing the designation. In resolving the matter, the burden of establishing confidentiality shall be on the Party who made the claim of confidentiality, *i.e.*, the Producing Party, but information designated as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER shall be deemed so designated until the matter is resolved.

4. Restrictions on Disclosure and Use

(a) CONFIDENTIALITY

Designated Material and the information derived from the Designated Material (excluding information which is derived lawfully from an independent source) shall not be given, shown, made available, discussed, or otherwise communicated in any manner, to any person not authorized to receive the information pursuant to the terms of this Protective Order, unless and to the extent that this Protective Order is otherwise modified by court order. Any summary,

[1] A "business day" is a day on which the Clerk's Office of the United States District Court for the District of Delaware is open.

compilation, notes, memoranda, analysis, electronic image, or database containing Designated Material shall be subject to the terms of this Protective Order to the same extent as the material or information from which the summary, compilation, notes, memoranda, analysis, electronic image, or database is derived.

(b) RESTRICTIONS ON USE

Absent an agreement of the Producing Party or an order to the contrary by this Court, each Party and all other persons bound by the terms of this Protective Order shall use any material designated as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER solely for purposes of these Actions and any appeal therefrom. Such Designated Material shall not be used for any other purpose, including, without limitation, any business, commercial, competitive, personal, or other purpose.

Specifically, HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER material obtained from these Actions shall not be submitted, used, or relied upon to prepare submissions to the U.S. Food and Drug Administration ("FDA") or U.S. Patent and Trademark Office ("USPTO"). Counsel of record for the parties shall exercise reasonable care to ensure that the information and documents governed by this Protective Order are (i) used only for the purpose specified herein, and (ii) disclosed only to authorized persons.

Absent consent of the Producing Party or further order of this Court, all outside counsel of record as defined in Paragraph 5(a) ~~and designated in-house representatives as defined in Paragraph 5(k)~~ who are substantively involved in the drafting or prosecution of claims in patents and/or patent applications relating to the Patents-in-Suit (including any continuations, continuations-in-part, or divisionals thereof claiming enalapril maleate oral solutions, or processes for making enalapril maleate oral solutions, or methods of treatment involving enalapril maleate

oral solutions) ~~are excluded from access to information designated HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER.~~will not have access to any documents containing the formulation for Bionpharma's product produced pursuant to ANDA No. 212408 ("Bionpharma Formulation Material"). For avoidance of doubt, the Bionpharma Formulation Material is information that discloses the entirety of Bionpharma's qualitative formulation, or the amount or concentration of any excipient contained in Bionpharma's ANDA product.. For the avoidance of doubt, being "substantively involved in the drafting or prosecution of claims in patents and/or patent applications" in the previous sentence shall mean the drafting or amending of claims, or providing direction or input on the drafting or amending of claims. Outside counsel of record as defined in Paragraph 5(a) ~~and designated in-house representatives as defined in Paragraph 5(k)~~ who do have access to ~~information designated HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER~~ Bionpharma Formulation Material cannot participate in such aforementioned activities during the pendency of these Actions, including any appeals therefrom, and for twelve (12) months after the last of these Actions is finally terminated.

For clarity, nothing in this agreement prohibits persons with access to HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER information from participating in opposition, reexamination, *inter partes* review, or other post-grant proceedings (except reissue) before the USPTO or before any foreign patent-granting authority (collectively, "Post-Grant Proceedings"). However, no outside counsel of record as defined in Paragraph 5(a) ~~or designated in-house representatives as defined in Paragraph 5(k)~~ who do have access to ~~information designated HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER~~ Bionpharma Formulation Material shall draft or provide any input on the drafting and/or amendment of claims in any Post-Grant Proceeding pertaining to enalapril maleate oral solutions during the pendency

of these Actions, including any appeals therefrom, and for twelve (12) months after these Actions are terminated, but such outside counsel of record as defined in Paragraph 5(a) and ~~designated~~ in-house representatives ~~as defined in Paragraph 5(k)~~ may otherwise fully participate in all such Post-Grant Proceedings pertaining to enalapril maleate oral solutions.

For the avoidance of doubt, outside counsel who do not have access to ~~information designated HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER~~ Bionpharma Formulation Material under this Protective Order ~~and in-house representatives other than those defined in Paragraph 5(k)~~ are not restricted in any manner by this Paragraph 4(b), and for example, may therefore freely draft, amend, and/or prosecute claims before the USPTO or before any foreign patent-granting authority. For the further avoidance of doubt, outside counsel who do not have "access" to Designated Material under this Protective Order means that such persons have not received Designated Material and will not attempt to obtain or view such Designated Material within the outside counsel firm's servers or other storage locations. All outside counsel of record in these Actions are presumed to have "access" to Designated Material as that term is used in this Paragraph and are subject to the restrictions of this Paragraph 4(b).

(c) MAINTENANCE OF DESIGNATED MATERIAL

Designated Material shall be maintained by the Receiving Party at a location and under circumstances to ensure that access is limited to only those persons entitled to have access pursuant to this Protective Order.

A Producing Party is free to do whatever it desires with its own Designated Material.

5. Access to Designated Material

Designated Material shall be available only to the following persons subject to the terms of Paragraph 6:

(a) Outside counsel of record to any Party in connection with these Actions, and the outside counsel's partners, associates, attorneys, data entry, information processing, computer support, artist, translating, stenographic, clerical, and paralegal employees or agents whose duties and responsibilities require and who actually have access to materials designated "HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER," subject to the restrictions set forth in Paragraph 4(b).

(b) The Court, including Judges, Magistrate Judges, law clerks, and clerical personnel of the Court before which these Actions are pending, and qualified court reporters;

(c) Approved consultants or experts and their staff, but excluding employees, officers, or directors of a named Party, retained by any of the Parties or their counsel to consult or testify in these Actions subject to the terms of Paragraph 6(a);

(d) Authors or drafters; addressees; anyone else who received the documents or information prior to the commencement of these Actions, or during these Actions, but only if they obtained the document or information outside of these Actions and not in violation of this Protective Order; provided that, in the case of former employees/consultants of the Producing Party permitted access pursuant to this provision, (i) the former employee/consultant reviews this Protective Order and executes the Agreement to be Bound by Protective Order, in the form shown in Exhibit A, which is attached hereto, prior to receiving Designated Material, (ii) the former employee/consultant of the Producing Party is not employed or retained by the Receiving Party, and (iii) Designated Material is shared with the former employee/consultant of the Producing Party only during a deposition taken in these Actions.

(e) Third party contractors and their employees involved in document management or copying services for these Actions;

(f) Graphics or design services retained by counsel for a Party for purposes of preparing demonstratives or other exhibits for deposition, trial, or other court proceedings in these Actions;

(g) Trial consulting services retained by a Party in these Actions;

(h) Persons who have been retained by a Party to provide translation or interpretation from one language to another;

(i) Third party testing laboratories and their staffs retained by any of the parties or their counsel for purposes of these Actions subject to the terms of Paragraph 6(b); and

(j) Any other person authorized to receive HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER Designated Material by order of the Court or by written agreement of the parties;

(k) Two (2) designated in-house representatives for each Party who have responsibility for maintaining and/or overseeing these Actions, as well as their secretarial and clerical staff~~, subject to the restrictions set forth in Paragraph 4(b)~~. Such representatives must execute a copy of the Agreement to be Bound by Protective Order (Exhibit A) prior to being given access to material designated~~s~~ as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER.

~~(k)~~(l) Azurity's in-house representatives as indicated in paragraph 5(k) are permitted to receive Designated Material produced by Bionpharma (upon execution of a copy of the Agreement to be Bound by Protective Order (Exhibit A)), and will be permitted access to Designated Material produced by Bionpharma pursuant to the restrictions contained in this Order. However, Azurity's in-house counsel will not have access to any documents containing Bionpharma Formulation Material. All Bionpharma Formulation Material will be redacted in any document prepared for

purposes of this litigation prior to sending to the in-house representatives indicated in paragraph 5(k).

6. Conditions on Access to Designated Material

(a) CONSULTANTS AND EXPERTS

Prior to a Receiving Party giving, showing, disclosing, making available, or communicating Designated Material to any expert or consultant under Paragraph 5(c), the Receiving Party shall:

(i) Provide written notice to the Producing Party identifying the expert or consultant and the following information:

(A) The expert's or consultant's business address, present employer and position (including a job description), and job history;

(B) a list of prior consulting relationships for companies involved in the development, manufacturing, marketing or sale of pharmaceutical products for the past five (5) years;

(C) the case name, number, and location of the court for any litigation in connection with which the expert or consultant has offered expert testimony, including through a declaration, report, or testimony at a deposition or trial, during the preceding five (5) years; and

(D) past or present relationship, if any, with the Receiving Party and/or Producing Party.

(E) Furthermore, the most recent curriculum vitae or resume of the expert or consultant shall be provided pursuant to this section. If the most recent curriculum vitae or resume of the expert or consultant

provides the information required pursuant to this Paragraph, then the information need not be separately provided.

(ii) Include with the notice, a copy of Agreement to be Bound by Protective Order (Exhibit A), signed by the expert or consultant.

(iii) The Producing Party shall be entitled to object to any disclosure of Designated Material to the expert or consultant within five (5) business days after receipt of the Agreement to be Bound by Protective Order by stating specifically in writing the reasons why the identified expert or consultant should not receive the Designated Material. Proper objectionable grounds include but are not limited to:

(A) The proposed expert or consultant is currently employed or anticipates future employment by Plaintiff or Defendant(s);

(B) The proposed expert or consultant is performing work-related to any product that is the subject of the Patents-in-Suit separate and apart from the work performed in connection with these Actions;

(C) The proposed expert or consultant is performing work related to any pharmaceutical drug product designed to directly compete with the products involved in these Actions.

(iv) If the Parties are unable to agree on disclosure of Designated Material to the expert or consultant, the objecting Party may apply to the Court for an order that disclosure is improper within ten (10) calendar days of its objection.

The burden of establishing the validity of written objections rests with the objecting Party. If the objecting Party does not apply to the Court within the prescribed period, the objection shall be deemed withdrawn by using the procedure set forth in Paragraph 7(h) of the Scheduling Order (No. 21-1286, D.I. 126).

(v) No disclosure of the Designated Material shall be made to the proposed expert or consultant until the time for serving objections to that expert or consultant has passed, or, in the event that a written objection is timely served and a submission to prevent disclosure is filed, until the Court has made a ruling thereon, and then, only in accordance with that ruling.

(vi) The filing and pendency of objections shall not limit, delay, or defer any disclosures of Designated Material to the expert or consultant as to whom no objection has been made, nor shall it delay or defer any other pending discovery unless the level of confidentiality bears directly on the objecting Party's ability to conduct that discovery.

(b) THIRD PARTY TESTING LABORATORIES

Counsel may use the services of third party testing laboratories to perform tests and analyses for the Actions on Designated Material marked HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER. Prior to a Receiving Party giving, showing, disclosing, making available, or communicating Designated Material to any third party testing laboratory pursuant to Paragraph 5(i) above, the Receiving Party shall:

(i) Provide written notice to the Producing Party, identifying the third party testing laboratory, the third party testing laboratory's business address, and

past or present relationship, if any, the third party testing laboratory has/had with the Receiving Party and/or Producing Party.

(ii) Include with the notice a copy of the Agreement to be Bound by Protective Order (Exhibit A), signed by a representative of the third party testing laboratory.

(iii) The Producing Party shall be entitled to object to the disclosure of Designated Material to the third party testing laboratory within ten (10) calendar days after receipt of the Acknowledgment of Protective Order by stating specifically in writing the reasons why the third party testing laboratory should not receive the Designated Material.

(iv) If the parties are unable to agree on the disclosure to the third party testing laboratory, the objecting Party may apply to the Court for an order that disclosure of Designated Material is improper within ten (10) calendar days of its objection. The burden of establishing the validity of written objections rests with the objecting Party. If the objecting Party does not apply to the Court within the prescribed period, the objection shall be deemed withdrawn by using the procedure set forth in Paragraph 7(h) of the Scheduling Order (No. 21-1286, D.I. 126).

(v) No disclosure of the Designated Material shall be made to the proposed third party testing laboratory until the time for serving objections to that third party testing laboratory has passed, or, in the event that a written objection is timely served and a submission to prevent disclosure is filed,

until the Court has made a ruling thereon, and then, only in accordance with that ruling.

(vi) The filing and pendency of objections shall not limit, delay, or defer any disclosures of Designated Material to third party testing laboratories as to whom no objection has been made, nor shall it delay or defer any other pending discovery unless the level of confidentiality bears directly on the objecting Party's ability to conduct that discovery.

(c) AUTHORIZATION AND ACKNOWLEDGEMENT

Persons or firms retained by Plaintiff or Defendant(s) to whom Designated Material is to be given, shown, disclosed, made available, or communicated in any way in accordance with this Protective Order (excluding the Court, *e.g.*, Judges, Magistrate Judges, law clerks, qualified court reporters, and clerical personnel of the Court before which these Actions are pending; and outside counsel of record to any Party in connection with these Actions and the outside counsel's partners, associates, attorneys, data entry, information processing, computer support, artist, translating, stenographic, clerical, and paralegal employees or agents whose duties and responsibilities require access to materials designated HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER), shall first execute an Agreement to be Bound by Protective Order (Exhibit A). Counsel for the Receiving Party shall keep in his or her files an original of each executed Acknowledgment of Protective Order until sixty (60) calendar days after the final termination of these Actions.

7. Procedures for Filing Papers with Designated Material

Designated Material may be included with, or referred to in, papers filed with the Court where these Actions are now pending or in any other court only in accordance with the following procedures:

(a) The Designated Material must be filed under seal in accordance with the applicable procedures set forth in the Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware and any Orders of the Court.

(b) All papers filed with the Court, including but not limited to pleadings and memoranda of law, which include all or any portion of information set forth in Designated Material must be filed under seal in accordance with the terms and procedures set forth in this Order, including the procedures for filing materials set forth above in Paragraph 7(a). Counsel for the Party filing papers with Designated Material shall be responsible for designating all papers filed with the Court as Designated Material and marked as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER depending on the contents of the papers being filed. The papers shall be subject to the terms of this Order.

8. Redacted Filings of Papers with Designated Material

Redacted versions of papers with Designated Materials filed under seal must be filed with the Court in accordance with the applicable procedures set forth in the Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware and any orders of the Court, and made publicly available provided that:

(a) All Designated Material set forth in the papers is deleted or obscured and all Designated Material is removed as exhibits; and

(b) Redacted versions of the papers are clearly marked "REDACTED PUBLIC VERSION" or a similar legend. Redacted versions of the papers also must clearly identify each place where information or exhibits have been deleted.

9. Unintentional Failure to Designate and Inadvertent Production

If, through inadvertence, regardless of reason or circumstances, a Producing Party provides any Designated Material in these Actions without designating and marking the Designated Material as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER, the Producing Party may subsequently inform the Receiving Party of the confidential nature of the disclosed Designated Material. The Receiving Party shall treat the disclosed Designated Material as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER upon receipt of written notice from the Producing Party, to the extent the Receiving Party has not disclosed this Designated Material to persons not authorized to receive that material under Paragraph 5.

Disclosure of Designated Material to persons not authorized to receive that material prior to receipt of the confidentiality designation shall not be deemed a violation of this Protective Order. However, in the event the material has been distributed in a manner inconsistent with the categorical designation, the Receiving Party promptly will take the steps reasonably necessary to (i) conform distribution to the categorical designation, *i.e.*, by retrieval and destruction of all copies of the Designated Material, or notes or extracts thereof, in the possession of the person(s) not authorized under this Protective Order to possess the Designated Material; (ii) advise the person(s) to whom disclosure was made that the material is confidential and should be treated as provided in the Protective Order, and (iii) confirm to the Producing Party in writing the retrieval or destruction. In the event the Receiving Party believes it has been prejudiced by any inadvertent failure to designate, the Receiving Party may contest the designation as set forth in Paragraph 3.

10. Privileged Information

The Parties agree that, as to objections based on attorney-client privilege, work product, or other immunity from discovery pursuant to Fed. R. Civ. P. 26 and Federal Rule of Evidence ("F.R.E.") 502, in response to requests for production pursuant to Fed. R. Civ. P. 34 and

interrogatories pursuant to Fed. R. Civ. P. 33, to the extent that a Party is required at the time of making such objection to provide information identifying documents or information withheld from production because of objections based on privilege or immunity, the information shall be provided in the form of a privilege log at a mutually agreed upon time on or before the close of fact discovery. The Parties agree that production of a privilege log at the mutually agreed upon time shall not constitute waiver of the asserted privilege or immunity as to any document or information.

Counsel shall exert their best efforts to identify documents or material protected by the attorney-client privilege, the attorney work-product doctrine, the common-interest doctrine, or any other privilege or immunity prior to the disclosure of any documents or material. If, however, a Party unintentionally regardless of reason or circumstances, discloses documents or material that is privileged or otherwise immune from discovery, the Party shall, promptly upon discovery of the disclosure, so advise the Receiving Party in writing, request the documents or material be returned or destroyed, and attach a privilege log entry within twenty (20) calendar days pertaining to the documents or material that is privileged or otherwise immune from discovery. If that request is made and the privilege log provided, no Party to the Actions shall thereafter assert that the disclosure waived any privilege or immunity.

It is further agreed that the Receiving Party will return or destroy the inadvertently produced documents or material, and all copies and derivations (including any notes or work product made therefrom), within five (5) business days of the Receiving Party's receipt of a written request for the return of the documents or material. The Receiving Party having returned or destroyed the inadvertently produced documents or material may thereafter seek production of the documents or material in accordance with the Federal Rules of Civil Procedure, but cannot assert

that the privilege has been waived due to the unintentional disclosure. These procedures are not intended to in any way limit the right of a Party to argue pursuant to F.R.E. 502 or any other law that any inadvertent production did not constitute a waiver, except that the Receiving Party shall not sequester or retain the inadvertently produced documents in any manner or for any purpose, including for purposes of challenging the privilege claim.

In the event that a Receiving Party, in good faith, believes that the document(s) or tangible item(s) that were withdrawn by the Party claiming privilege are not properly subject to a claim of attorney-client privilege, work product immunity, or any other privilege or immunity, the Receiving Party may only use the privilege log as the basis for any motion to compel, and not the contested document. For the avoidance of doubt, the Court (including Judges, Magistrate Judges, law clerks, and clerical personnel of the Court before which these Actions are pending) is permitted to review the contested document in-camera in conjunction with a motion to compel.

11. Information Not Covered by Protective Order

The restrictions set forth in this Protective Order shall not apply to information which is in the possession of or otherwise known to the Receiving Party or the public before the date of its transmission to the Receiving Party, or which lawfully comes into the possession of or becomes known to the Receiving Party or lawfully comes into the possession of or otherwise becomes known to the public after the date of its transmission to the Receiving Party, provided that the information does not become publicly known by any act or omission of the Receiving Party which would be in violation of this Protective Order.

12. Responsibility of Attorneys

Outside counsel of record shall be responsible for providing a copy of this Protective Order to all persons entitled access to Designated Material under Paragraph 5 and to employ reasonable

measures to control duplication of, access to, and distribution of copies of materials so designated. All copies, extracts and translations must be appropriately marked and are subject to Paragraph 13 of this Protective Order.

13. Final Disposition

Upon termination, settlement, or final judgment of these Actions, including exhaustion of all appeals, the originals and all copies of Designated Material shall be either destroyed or turned over to the Producing Party, or to their respective outside counsel, within ninety (90) calendar days. However, outside counsel may retain court filings and other pleadings and discovery served; trial, deposition, and hearing transcripts; correspondence; expert reports; attorney and consultant work product; and deposition and trial exhibits for archival purposes. If Designated Material is destroyed pursuant to this Paragraph, outside counsel for the Receiving Party shall provide to outside counsel for the Producing Party a certification that the destruction was performed. The provisions of this Protective Order insofar as it restricts the disclosure, communication of, and use of Designated Material produced hereunder shall continue to be binding after the conclusion of these Actions.

14. No Limitation on Other Rights

This Protective Order shall be without prejudice to the right of any Party to oppose production of any information on any and all grounds other than confidentiality.

15. Release from or Modification of Protective Order

This Protective Order is entered without prejudice to the right of any Party to apply to the Court at any time for additional protection; or to release, rescind, or modify the restrictions of this Protective Order; to determine whether a particular person shall be entitled to receive any particular information; or to seek relief from inadvertent disclosure of privileged or work-product

information. This Protective Order does not preclude all of the parties to this Protective Order from entering into any stipulation (in writing or on the record) constituting a modification of this Protective Order. On any application seeking disclosures beyond those authorized by this Protective Order, the burden will be on the Receiving Party to justify the disclosure.

16. Other Proceedings

By entering this Protective Order and limiting the disclosure of information in these Actions, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or Party subject to this Protective Order who becomes subject to a motion to disclose another Party's information designated HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER pursuant to this Protective Order in another case shall promptly notify that other Party of the motion so that the other Party may have an opportunity to appear and be heard on whether that information should be disclosed.

17. Discovery from Third Parties

If discovery is sought of a person not a Party to these Actions (*i.e.*, a third party) requiring disclosure of said third party's Designated Material, the Designated Material disclosed by the third party will be accorded the same protection as the parties' Designated Material, and will be subject to the same procedures as those governing disclosure of the parties' Designated Material pursuant to this Protective Order. Should a Party to these Actions have a good faith basis that the third party production may contain a Party's confidential information, that Party shall be allowed to designate that information according to this Protective Order within twenty-one (21) calendar days of receipt of that production.

18. Admissibility

Nothing herein shall be construed to affect in any way the evidentiary admissibility of any document, testimony, or other matter at any court proceeding related to the Action. The marking of Designated Material as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER pursuant to this Protective Order shall not, for that reason alone, bar its introduction or use at any court proceeding related to these Actions pursuant to the terms and conditions as the Court ~~f~~may deem appropriate, consistent with the need for a complete and accurate record of the proceedings, provided, however, that every effort shall be made, through the use of procedures agreed upon by the Parties or otherwise, to preserve the confidentiality of Designated Material.

19. Non-Party Request and/or Subpoena of Designated Material

If a Receiving Party receives a subpoena or other compulsory process from a non-party to this Protective Order seeking production or other disclosure of a Producing Party's Designated Material, that Receiving Party shall give written notice to outside counsel of record for the Producing Party within five (5) business days after receipt of the subpoena or other compulsory process identifying the specific Designated Material sought and enclosing a copy of the subpoena or other compulsory process. If the Producing Party timely seeks a protective order, the Receiving Party to whom the subpoena or other compulsory process was issued or served shall not produce the Designated Material requested prior to receiving a court order or consent of the Producing Party. In the event that Designated Material is produced to the non-party, the material shall be treated as HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER pursuant to this Protective Order.

20. Unintentional Disclosure of Designated Material

If Designated Material, or any portion thereof, is disclosed by the Receiving Party, through inadvertence or otherwise, to any person or party not authorized under this Protective Order, then the Receiving Party shall use its best efforts to retrieve immediately all copies of the Designated Material, and to bind the person to the terms of this Protective Order. In that event, the Receiving Party shall also (i) promptly inform that person of all the provisions of this Protective Order; (ii) identify that person immediately to the Producing Party; and (iii) request that person to execute the Agreement to be Bound by Protective Order (Exhibit A) and confirm destruction or return of the material and all copies and derivations (including any notes or work product made therefrom).

21. Counsel's Right to Provide Advice

Nothing in this Protective Order shall bar or otherwise restrict any counsel herein from rendering advice to the counsel's Party-client with respect to these Actions, and in the course thereof, relying upon an examination of Designated Material, provided, however, that in rendering advice and in otherwise communicating with the Party-client, the counsel shall not disclose any Designated Material to anyone not authorized to receive Designated Material pursuant to the terms of this Protective Order.

22. No Contract

To the extent that the parties have agreed on the terms of this Protective Order, this stipulation is for the Court's consideration and approval as an order. The Parties' stipulation shall not be construed to create a contract between the Parties, or between the Parties and their respective counsel.

23. Effective Date

This Protective Order shall be effective on the date of its execution, provided that all material previously produced shall be deemed HIGHLY CONFIDENTIAL—SUBJECT TO

PROTECTIVE ORDER unless and until they are re-designated by the Producing Party or by further order of the Court.

24. Termination

The termination of these Actions shall not automatically terminate the effectiveness of this Protective Order. Persons subject to this Protective Order shall be bound by the confidentiality obligations of this Protective Order until the Producing Party agrees otherwise in writing or this Court (or any other court or competent jurisdiction) orders otherwise.

SO ORDERED this _____ day of _____, 2022

_____

United States District Judge

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

draft

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September 13, 2022~~September 139, 2022~~

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	C.A. No. 21-1286~~-MSG~~ (LPS)
v.	)	C.A. No. 21-1455~~-MSG~~ (LPS)
	)	
BIONPHARMA INC.,	)	
	)	
Defendant.	)	

AGREEMENT TO BE BOUND BY PROTECTIVE ORDER

I, _____, state that:

1. My present employer is _____; and my work address is _____

_____.

2. My present occupation or job description is _____

_____.

3. My relationship to a Party/the Parties in the Action(s) is _____

_____.

4. I have carefully read and understood the provisions of the Protective Order in these Actions signed by the Court, and I will comply with and agree to be bound by all provisions of the Protective Order.

5. I will hold in confidence and not disclose to anyone not qualified under the Protective Order any Discovery Material designated HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER (*i.e.*, Designated Material) or any words, summaries, abstracts, or indices of such information disclosed to me.

6. I will only use Designated Material disclosed to me solely for the purposes of these Actions.

7. No later than the final conclusion of the last of these Actions, I will return, or certify complete destruction of, all Designated Material and summaries, abstracts, and indices thereof which come into my possession, and documents or things which I have prepared relating thereto, to outside counsel for the Party/Parties for whom I am/was employed or have been retained.

8. I agree to submit myself to the jurisdiction of the United States District Court for the District of Delaware, or other jurisdiction where these Actions may be pending, for the purpose of enforcing the terms of this undertaking.

9. I understand that if I violate the provisions of the Protective Order, I will be in violation of a Court order and subject to sanctions or other remedies that may be imposed by the Court and potentially liable in a civil action for damages.

10. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Date: _____ _____

[Signature]

_____

[Printed Name]

EXHIBIT 4

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https://dailymed.nlm.nih.gov › dailymed › drugInfo

Label: ENALAPRIL MALEATE ORAL SOLUTION - DailyMed

Enalapril maleate oral solution is indicated for the treatment of symptomatic heart failure, usually in combination with diuretics and digitalis. In these ...

Angioedema and... · Hypotension · Other Adverse Reactions from... · Pregnancy

https://professionals.optumrx.com › publications › library

Epaned® (enalapril) – First-time generic

Aug 16, 2021 — August 16, 2021 - **Bionpharma** launched an AB-rated generic version of Azurity's Epaned (**enalapril**) oral solution.

https://www.jdsupra.com › legalnews › silvergate-phar...

Silvergate Pharms. Inc. v. Bionpharma Inc. | Robins Kaplan LLP

Aug 2, 2021 — Nature of Case and Issue(s) Presented: The patents-in-suit claimed **enalapril** formulations for the FDA-approved medication Epaned, which was an ...

https://www.accessdata.fda.gov › appletter PDF

Enalapril Maleate Oral Solution - Accessdata.fda.gov

Dec 28, 2020 — **Bionpharma** Inc. 600 Alexander Road, Suite 2-4B. Princeton, NJ 08540. Attention: Usha Sankaran. Associate Vice President, Regulatory Affairs.

6 pages

ENALAPRIL MALEATE ORAL SOLUTION- enalapril maleate solution
Bionpharma Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use ENALAPRIL MALEATE ORAL SOLUTION safely and effectively. See full prescribing information for ENALAPRIL MALEATE ORAL SOLUTION.

ENALAPRIL MALEATE oral solution

Initial U.S. Approval: 1985

WARNING: FETAL TOXICITY

See full prescribing information for complete boxed warning.

- **When pregnancy is detected, discontinue enalapril maleate oral solution as soon as possible. (5.1)**
- **Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus. (5.1)**

INDICATIONS AND USAGE

Enalapril is an angiotensin-converting enzyme inhibitor indicated for:

- treatment of symptomatic heart failure. (1.2)
- treatment of asymptomatic left ventricular dysfunction, to decrease the rate of development of overt heart failure and reduce hospitalization for heart failure. (1.3)

DOSAGE AND ADMINISTRATION

Heart Failure: Initiate at 2.5 mg twice daily. Titrate up to 20 mg twice daily as tolerated. (2.2)
Asymptomatic Left Ventricular Dysfunction: Initiate at 2.5 mg twice daily. Titrate up to 10 mg twice daily. (2.3)
Enalapril maleate oral solution is a ready-to-use solution intended for oral use only.

DOSAGE FORMS AND STRENGTHS

Enalapril maleate oral solution is a ready-to-use oral solution: 1 mg/mL enalapril maleate, USP. (3)

CONTRAINDICATIONS

- Hypersensitivity related to previous treatment with an ACEI. (4)
- Hereditary or idiopathic angioedema. (4)
- Do not co-administer aliskiren in patients with diabetes. (4)
- In combination with a neprilysin inhibitor. (4)

WARNINGS AND PRECAUTIONS

- Angioedema and Anaphylactoid Reactions. (5.2)
- Impaired Renal Function: Assess renal function. (5.5)
- Hyperkalemia. (5.6)

ADVERSE REACTIONS

- The most common adverse reactions for patients treated for heart failure (>6%) were hypotension and dizziness. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Bionpharma Inc. at 1-888-235-BION or 1-888-235-2466 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- In patients who are elderly, volume-depleted (as on diuretic therapy), or with compromised renal function, use with NSAIDs, including selective COX-2 inhibitors, may result in deterioration of renal function, including renal failure. Monitor renal function periodically. (7.1)
- Dual inhibition of the renin-angiotensin system: Increased risk of renal impairment, hypotension and hyperkalemia. (7.2)

- Avoid potassium sparing agents in patients with heart failure. (7.3)
- Monitor serum lithium levels frequently. (7.4)

USE IN SPECIFIC POPULATIONS

- Enalapril is not recommended in neonates and in pediatric patients with glomerular filtration rate <30 mL/min/1.73 m ^{2}. (8.4)
- Lactation: Advise not to breastfeed. (8.2)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 6/2022

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

WARNING: FETAL TOXICITY

- **When pregnancy is detected, discontinue enalapril maleate oral solution as soon as possible. *[See Warnings and Precautions (5.1)]***
- **Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus. *[See Warnings and Precautions (5.1)]***

1 INDICATIONS AND USAGE

1.2 Heart Failure

Enalapril maleate oral solution is indicated for the treatment of symptomatic heart failure, usually in combination with diuretics and digitalis. In these patients, enalapril maleate oral solution increases survival and decreases the frequency of hospitalization.

1.3 Asymptomatic Left Ventricular Dysfunction

In clinically stable asymptomatic patients with left ventricular dysfunction (ejection fraction ≤35 percent), enalapril maleate oral solution decreases the rate of development of overt heart failure and decreases the incidence of hospitalization for heart failure.

2 DOSAGE AND ADMINISTRATION

2.2 Heart Failure

The recommended initial dose is 2.5 mg twice a day titrated up to a maximum of 20 mg twice a day, as tolerated. Doses are usually given in combination with diuretics and digitalis.

In patients with hyponatremia (serum sodium less than 130 mEq/L) or serum creatinine greater than 1.6 mg/dL, the recommended initial dose is 2.5 mg once daily.

Diuretic dose may need to be adjusted to minimize hypovolemia and hypotension. The appearance of hypotension after the initial dose of enalapril maleate oral solution does not preclude subsequent careful dose titration with the drug, following effective management of the hypotension.

2.3 Asymptomatic Left Ventricular Dysfunction

The recommended initial dose is 2.5 mg twice a day titrated up to a maximum of 10 mg twice a day, as tolerated. Diuretic dose may need to be adjusted.

3 DOSAGE FORMS AND STRENGTHS

Enalapril maleate oral solution is a ready-to-use oral solution that contains 1 mg/mL of enalapril maleate, USP. It is a clear, colorless solution with a mixed berry flavor packaged in a 150 mL white, round, high-density polyethylene bottle with a white, polypropylene, child-resistant cap and tamper-evident seal. Each bottle contains 150 mL.

4 CONTRAINDICATIONS

Enalapril is contraindicated in patients with:

- a history of angioedema or hypersensitivity related to previous treatment with an angiotensin converting enzyme (ACE) inhibitor. *[see Warnings and Precautions (5.2)]*
- hereditary or idiopathic angioedema. *[see Warnings and Precautions (5.2)]*

Do not co-administer aliskiren with enalapril in patients with diabetes *[see Drug Interactions (7.2)]* .

Enalapril is contraindicated in combination with a neprilysin inhibitor (e.g., sacubitril). Do not administer enalapril within 36 hours of switching to or from sacubitril/valsartan, a neprilysin inhibitor *[see Warnings and Precautions (5.2)]* .

5 WARNINGS AND PRECAUTIONS

5.1 Fetal Toxicity

Use of drugs that act on the renin-angiotensin system during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity and death.

Resulting oligohydramnios can be associated with fetal lung hypoplasia and skeletal deformations. Potential neonatal adverse effects include skull hypoplasia, anuria, hypotension, renal failure, and death. When pregnancy is detected, discontinue enalapril as soon as possible *[see Use in Specific Populations (8.1)]* .

5.2 Angioedema and Anaphylactoid Reactions

Angioedema

Head and Neck Angioedema

Angioedema of the face, extremities, lips, tongue, glottis and/or larynx, including some fatal reactions, have occurred in patients treated with angiotensin converting enzyme inhibitors, including enalapril, at any time during treatment. Patients with involvement of the tongue, glottis or larynx are likely to experience airway obstruction, especially those with a history of airway surgery. Enalapril should be promptly discontinued and appropriate therapy and monitoring should be provided until complete and sustained resolution of signs and symptoms of angioedema has occurred.

Patients with a history of angioedema unrelated to ACE inhibitor therapy may be at increased risk of angioedema while receiving an ACE inhibitor *[see Contraindications (4)]* . ACE inhibitors have been associated with a higher rate of angioedema in black than in non-black patients.

Patients receiving co-administration of ACE inhibitor and mTOR (mammalian target of rapamycin) inhibitor (e.g., temsirolimus, sirolimus, everolimus) therapy or a neprilysin inhibitor may be at increased risk for angioedema *[see Drug Interactions (7.6, 7.7)].*

Intestinal Angioedema

Intestinal angioedema has occurred in patients treated with ACE inhibitors. These patients presented with abdominal pain (with or without nausea or vomiting); in some cases there was no prior history of facial angioedema and C-1 esterase levels were normal. In some cases, the angioedema was diagnosed by procedures including abdominal CT scan or ultrasound, or at surgery, and symptoms resolved after stopping the ACE inhibitor.

Anaphylactoid Reactions

Anaphylactoid Reactions during Desensitization

Two patients undergoing desensitizing treatment with hymenoptera venom while receiving ACE inhibitors sustained life-threatening anaphylactoid reactions.

Anaphylactoid Reactions during Dialysis

Sudden and potentially life-threatening anaphylactoid reactions have occurred in some patients dialyzed with high-flux membranes and treated concomitantly with an ACE inhibitor. In such patients, dialysis must be stopped immediately, and aggressive therapy for anaphylactoid reactions must be initiated. Symptoms have not been relieved by antihistamines in these situations. In these patients, consideration should be given to using a different type of dialysis membrane or a different class of antihypertensive agent. Anaphylactoid reactions have also been reported in patients undergoing low-density lipoprotein apheresis with dextran sulfate absorption.

5.3 Hypotension

Enalapril can cause symptomatic hypotension, sometimes complicated by oliguria, progressive azotemia, acute renal failure or death. Patients at risk of excessive hypotension include those with the following conditions or characteristics: heart failure with systolic blood pressure below 100 mmHg, ischemic heart disease, cerebrovascular disease, hyponatremia, high dose diuretic therapy, renal dialysis, or severe volume and/or salt depletion of any etiology.

In these patients, enalapril should be started under very close medical supervision and such patients should be followed closely for the first two weeks of treatment and

whenever the dose of enalapril and/or diuretic is increased.

Symptomatic hypotension is also possible in patients with severe aortic stenosis or hypertrophic cardiomyopathy.

Surgery/Anesthesia

In patients undergoing major surgery or during anesthesia with agents that produce hypotension, enalapril may block angiotensin II formation secondary to compensatory renin release. If hypotension occurs and is considered to be through this mechanism, it can be corrected by volume expansion.

5.4 Hepatic Failure

Rarely, ACE inhibitors have been associated with a syndrome that starts with cholestatic jaundice and progresses to fulminant hepatic necrosis, and (sometimes) death. The mechanism of this syndrome is not understood. Patients receiving ACE inhibitors who develop jaundice or marked elevations of hepatic enzymes should discontinue the ACE inhibitor and receive appropriate medical follow-up.

5.5 Impaired Renal Function

Monitor renal function in patients treated with enalapril. Changes in renal function including acute renal failure can be caused by drugs that inhibit the renin-angiotensin system. Patients whose renal function may depend in part on the activity of the renin-angiotensin system (e.g., patients with renal artery stenosis, chronic kidney disease, severe congestive heart failure, post-myocardial infarction or volume depletion) may be at particular risk of developing acute renal failure on enalapril. Consider withholding or discontinuing therapy in patients who develop a clinically significant decrease in renal function on enalapril *[see Adverse Reactions (6.2), Drug Interactions (7.2, 7.3)]* .

5.6 Hyperkalemia

Serum potassium should be monitored in patients receiving enalapril. Drugs that inhibit the renin-angiotensin system can cause hyperkalemia. Risk factors for the development of hyperkalemia include renal insufficiency, diabetes mellitus, and the concomitant use of potassium-sparing diuretics, potassium supplements and/or potassium-containing salt substitutes *[see Drug Interactions (7.3)]* .

6 ADVERSE REACTIONS

The following adverse reactions are described elsewhere:

- Angioedema *[see Warnings and Precautions (5.2)]*
- Hypotension *[see Warnings and Precautions (5.3)]*
- Hepatic failure *[see Warnings and Precautions (5.4)]*
- Renal impairment *[see Warnings and Precautions (5.5)]*
- Hyperkalemia *[see Warnings and Precautions (5.6)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Enalapril has been evaluated for safety in more than 10,000 patients, including over 1,000 patients treated for one year or more.

In clinical trials, discontinuation of therapy for clinical adverse experiences was required in 5.7% of patients with heart failure.

Heart Failure

In patients treated for heart failure, there was an increased incidence of hypotension 6.7 percent versus 0.6 percent in placebo and dizziness 7.9 percent versus 0.6 percent in placebo.

6.2 Other Adverse Reactions from Clinical Studies or Postmarketing Experience

The following adverse reactions have been reported in clinical studies or postmarketing experience with enalapril. Because some of these reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Other serious clinical adverse experiences occurring since the drug was marketed or adverse experiences occurring in 0.5 to 1.0% of patients with hypertension or heart failure in clinical trials are listed below and, within each category, are in order of decreasing severity.

Cardiovascular: Cardiac arrest; myocardial infarction or cerebrovascular accident, possibly secondary to excessive hypotension in high risk patients *[see Warnings and Precautions (5.3)]* ; pulmonary embolism and infarction; pulmonary edema; rhythm disturbances, including atrial tachycardia and bradycardia; atrial fibrillation; palpitation; Raynaud's phenomenon.

Digestive: Ileus, pancreatitis, melena, anorexia, dyspepsia, constipation, glossitis, stomatitis, dry mouth.

Hematologic: Rare cases of neutropenia, thrombocytopenia, and bone marrow depression.

Musculoskeletal: Muscle cramps.

Nervous/Psychiatric: Depression, confusion, ataxia, somnolence, insomnia, nervousness, peripheral neuropathy (e.g., paresthesia, dysesthesia), dream abnormality.

Respiratory: Bronchospasm, rhinorrhea, sore throat and hoarseness, asthma, upper respiratory infection, pulmonary infiltrates, eosinophilic pneumonitis.

Skin: Exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson syndrome, pemphigus, herpes zoster, erythema multiforme, urticaria, pruritus, alopecia, flushing, diaphoresis, photosensitivity.

Special Senses: Blurred vision, taste alteration, anosmia, tinnitus, conjunctivitis, dry eyes, tearing.

Urogenital: Flank pain, gynecomastia, impotence.

Miscellaneous: A symptom complex has been reported which may include some or all of the following: a positive ANA, an elevated erythrocyte sedimentation rate,

arthralgia/arthritis, myalgia/myositis, fever, serositis, vasculitis, leukocytosis, eosinophilia, photosensitivity, dermatologic manifestations.

7 DRUG INTERACTIONS

7.1 Non-Steroidal Anti-Inflammatory Agents (NSAIDs) Including Selective Cyclooxygenase-2 Inhibitors (COX-2 Inhibitors)

In patients who are elderly, volume-depleted (including those on diuretic therapy), or with compromised renal function, co-administration of NSAIDs, including selective COX-2 inhibitors, with ACE inhibitors, including enalapril, may result in deterioration of renal function, including possible acute renal failure. These effects are usually reversible. Monitor renal function periodically in patients receiving enalapril and NSAID therapy.

In a clinical pharmacology study, indomethacin or sulindac was administered to hypertensive patients receiving enalapril maleate. In this study, there was no evidence of a blunting of the antihypertensive action of enalapril maleate. However, reports suggest that NSAIDs may diminish the antihypertensive effect of ACE inhibitors.

7.2 Dual Blockade of the Renin-Angiotensin System (RAS)

Dual blockade of the RAS with angiotensin receptor blockers, ACE inhibitors, or aliskiren is associated with increased risks of hypotension, hyperkalemia, and changes in renal function (including acute renal failure) compared to monotherapy. In most patients no benefit has been associated with using two RAS inhibitors concomitantly. In general, avoid combined use of RAS inhibitors. Closely monitor blood pressure, renal function and electrolytes in patients on enalapril and other agents that affect the RAS.

Do not co-administer aliskiren with enalapril in patients with diabetes. Avoid use of aliskiren with enalapril in patients with renal impairment (GFR <60 mL/min).

7.3 Agents Increasing Serum Potassium

Enalapril attenuates potassium loss caused by thiazide-type diuretics. Potassium-sparing diuretics (e.g., spironolactone, triamterene, or amiloride), potassium supplements, or potassium-containing salt substitutes may lead to significant increases in serum potassium.

7.4 Lithium

Lithium toxicity has been reported in patients receiving enalapril and lithium concomitantly which was generally reversible. It is recommended that serum lithium levels be monitored frequently if enalapril is administered concomitantly with lithium.

7.5 Gold

Nitritoid reactions (symptoms include facial flushing, nausea, vomiting, and hypotension) have been reported rarely in patients on therapy with injectable gold (sodium aurothiomalate) and concomitant ACE inhibitor therapy including enalapril.

7.6 mTOR Inhibitors

Patients taking concomitant mTOR inhibitor (e.g., temsirolimus, sirolimus, everolimus)

therapy may be at increased risk for angioedema *[see Warnings and Precautions (5.2)]* .

7.7 Neprilysin Inhibitor

Patients taking concomitant neprilysin inhibitors may be at increased risk for angioedema *[see Warnings and Precautions (5.2)]* .

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Enalapril can cause fetal harm when administered to a pregnant woman. Use of drugs that act on the renin-angiotensin system during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity and death. Most epidemiologic studies examining fetal abnormalities after exposure to antihypertensive use in the first trimester have not distinguished drugs affecting the renin-angiotensin system from other antihypertensive agents. When pregnancy is detected, discontinue enalapril as soon as possible. The estimated background risk of major birth defects and miscarriage for the indicated population(s) are unknown. In the general U.S. population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Clinical Considerations

Adverse reactions in the fetus or in neonates with a history of in utero exposure to enalapril maleate.

Use of drugs that act on the renin-angiotensin system during the second and third trimesters of pregnancy can result in the following: reduced fetal renal function leading to anuria and renal failure, oligohydramnios, fetal lung hypoplasia, skeletal deformations, including skull hypoplasia, hypotension, and death. In the unusual case that there is no appropriate alternative to therapy with drugs affecting the renin-angiotensin system for a particular patient, apprise the mother of the potential risk to the fetus.

Perform serial ultrasound examinations to assess the intra-amniotic environment. Fetal testing may be appropriate, based on the week of pregnancy. Patients and physicians should be aware, however, that oligohydraminos may not appear until after the fetus has sustained irreversible injury. Closely observe infants with histories of *in utero* exposure to enalapril for hypotension, oliguria, and hyperkalemia. If oliguria or hypotension occurs in neonates with a history of *in utero* exposure to enalapril, support blood pressure and renal perfusion. Exchange transfusions or dialysis may be required as a means of reversing hypotension and substituting for disordered renal function.

8.2 Lactation

Risk Summary

Enalapril and enalaprilat have been detected in human breast milk. Because of the potential for severe adverse reactions in the breastfed infant, including hypotension, hyperkalemia, and renal impairment, advise women not to breastfeed during treatment with enalapril.

8.4 Pediatric Use

Neonates with a history of in utero exposure to enalapril maleate

If oliguria or hypotension occurs, direct attention toward support of blood pressure and renal perfusion. Exchange transfusions or dialysis may be required as a means of reversing hypotension and/or substituting for disordered renal function. Enalapril, which crosses the placenta, has been removed from neonatal circulation by peritoneal dialysis with some clinical benefit, and theoretically may be removed by exchange transfusion, although there is no experience with the latter procedure.

Pediatric patients with heart failure or asymptomatic left ventricular dysfunction

Safety and effectiveness of enalapril have not been established in pediatric patients with heart failure or asymptomatic left ventricular dysfunction.

8.5 Geriatric Use

This drug is known to be substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

8.6 Race

ACE inhibitors, including enalapril, as monotherapy have an effect on blood pressure that is less in black patients than in non-blacks.

8.7 Renal Impairment

Use a lower initial dose of enalapril in patients undergoing hemodialysis and in patients whose eGFR is ≤ 30 mL/min *[see Clinical Pharmacology (12.3)]* .

10 OVERDOSAGE

Limited data are available in regard to overdosage in humans.

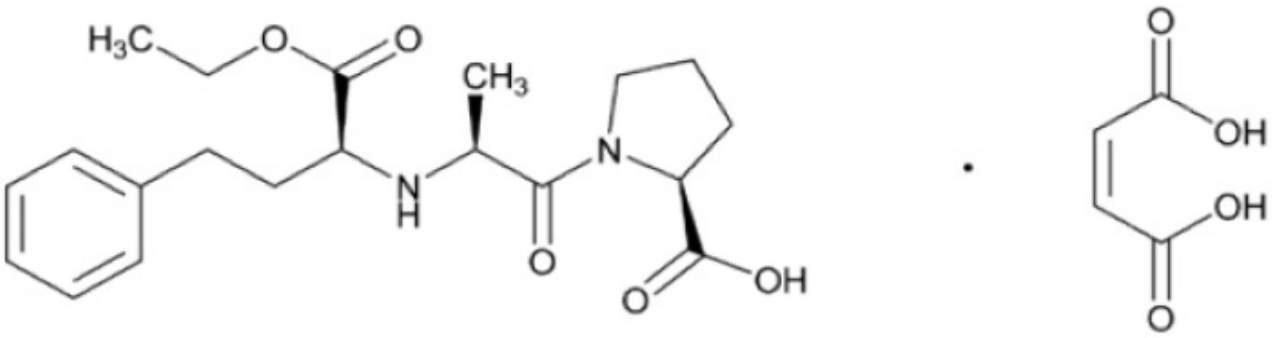
Single oral doses of enalapril above 1,000 mg/kg and ≥1,775 mg/kg were associated with lethality in mice and rats, respectively.

The most likely manifestation of overdosage would be hypotension, for which the usual treatment would be intravenous infusion of normal saline solution.

Enalaprilat may be removed from general circulation by hemodialysis and has been removed from neonatal circulation by peritoneal dialysis.

11 DESCRIPTION

Enalapril maleate oral solution is the maleate salt of enalapril, the ethyl ester prodrug of a long-acting angiotensin-converting enzyme inhibitor, enalaprilat. Enalapril maleate is chemically described as (S)-1-[N-[1-(ethoxycarbonyl)-3-phenylpropyl]-L-alanyl]-L-proline, (Z)-2-butenedioate salt (1:1). Its empirical formula is $C_{20}H_{28}N_2O_5 \cdot C_4H_4O_4$, and its structural formula is:



Enalapril maleate, USP is an off-white, crystalline powder with a molecular weight of 492.52. It is practically insoluble in n-heptane (non-polar organic solvent), slightly soluble in acetone (semi-polar organic solvent), sparingly soluble in water, soluble in alcohol, freely soluble in methanol and in dimethyl formamide.

Enalapril maleate oral solution is a ready-to-use oral solution. Each 1 mL contains 1 mg of enalapril maleate, USP equivalent to 0.764 mg of enalapril. Inactive ingredients include methylparaben, mixed berry flavor, propylene glycol, propylparaben, purified water, sorbitol solution 70%, and sucralose. It may also contain hydrochloric acid or sodium hydroxide for pH adjustment. Enalapril maleate oral solution is clear and colorless.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Enalapril, after hydrolysis to enalaprilat, inhibits angiotensin-converting enzyme (ACE) in human subjects and animals. ACE is a peptidyl dipeptidase that catalyzes the conversion of angiotensin I to the vasoconstrictor substance, angiotensin II. Angiotensin II also stimulates aldosterone secretion by the adrenal cortex. The beneficial effects of enalapril in heart failure appear to result primarily from suppression of the renin-angiotensin-aldosterone system. Inhibition of ACE results in decreased plasma angiotensin II, which leads to decreased vasopressor activity and to decreased aldosterone secretion. Although the latter decrease is small, it results in small increases of serum potassium. In hypertensive patients treated with enalapril maleate tablets alone for up to 48 weeks, mean increases in serum potassium of approximately 0.2 mEq/L were observed. In patients treated with enalapril maleate tablets plus a thiazide diuretic, there was essentially no change in serum potassium *[see Warnings and Precautions (5.6)]* . Removal of angiotensin II negative feedback on renin secretion leads to increased plasma renin activity.

ACE is identical to kininase, an enzyme that degrades bradykinin. Whether increased levels of bradykinin, a potent vasodepressor peptide, play a role in the therapeutic effects of enalapril remains to be elucidated.

12.2 Pharmacodynamics

Heart Failure

In trials in patients treated with digitalis and diuretics, treatment with enalapril resulted in decreased systemic vascular resistance, blood pressure, pulmonary capillary wedge

pressure and heart size, and increased cardiac output and exercise tolerance. Heart rate was unchanged or slightly reduced, and mean ejection fraction was unchanged or increased. There was a beneficial effect on severity of heart failure as measured by the New York Heart Association (NYHA) classification and on symptoms of dyspnea and fatigue. Hemodynamic effects were observed after the first dose, and appeared to be maintained in uncontrolled studies lasting as long as four months. Effects on exercise tolerance, heart size, and severity and symptoms of heart failure were observed in placebo-controlled studies lasting from eight weeks to over one year.

12.3 Pharmacokinetics

The pharmacokinetics of ready-to-use enalapril maleate oral solution was shown to be bioequivalent to that of reconstituted enalapril maleate powder for oral solution under fasted conditions.

Reconstituted enalapril maleate powder for oral solution was shown to be bioequivalent to Vasotec ® tablets. Reconstituted enalapril maleate powder for oral solution was also evaluated under fed and fasted conditions. A high-fat meal reduced the C_{max} of enalapril and enalaprilat by 46% and 36%, respectively. The exposure, as measured by AUC, to enalaprilat was reduced by 23%. The time to peak concentrations (C_{max}) was delayed by 20 minutes for enalapril and 62 minutes for enalaprilat. The trough plasma concentrations of enalapril (from 6 to 12 hours) and enalaprilat (from 16 to 36 hours) are similar between fasted and fed administrations.

Adults

Following oral administration of enalapril maleate tablets, peak serum concentrations of enalapril occur within about one hour. Based on urinary recovery, the extent of absorption of enalapril is approximately 60%. Enalapril absorption is not influenced by the presence of food in the gastrointestinal tract. Following absorption, enalapril is hydrolyzed to enalaprilat, which is a more potent angiotensin-converting enzyme inhibitor than enalapril; enalaprilat is poorly absorbed when administered orally. Peak serum concentrations of enalaprilat occur three to four hours after an oral dose of enalapril maleate. Excretion of enalapril is primarily renal.

Approximately 94% of the dose is recovered in the urine and feces as enalaprilat or enalapril. The principal components in urine are enalaprilat, accounting for about 40% of the dose, and intact enalapril. There is no evidence of metabolites of enalapril, other than enalaprilat.

The serum concentration profile of enalaprilat exhibits a prolonged terminal phase, apparently representing a small fraction of the administered dose that has been bound to ACE. The amount bound does not increase with dose, indicating a saturable site of binding. The effective half-life for accumulation of enalaprilat following multiple doses of enalapril maleate is 11 hours.

The disposition of enalapril and enalaprilat in patients with renal insufficiency is similar to that in patients with normal renal function until the glomerular filtration rate is 30 mL/min or less. With glomerular filtration rate ≤30 mL/min, peak and trough enalaprilat levels increase, time to peak concentration increases, and time to steady state may be delayed. The effective half-life of enalaprilat following multiple doses of enalapril maleate is prolonged at this level of renal insufficiency. Enalaprilat is dialyzable at the rate of 62 mL/min. Administering enalapril 1 hour after hemodialysis led to a reduction of

approximately 50% in the enalaprilat AUC $_{0\text{-}6\ h}$ compared to off dialysis days.

Pediatric Patients

A multiple dose pharmacokinetic study was conducted in 40 hypertensive male and female pediatric patients aged 2 months to ≤16 years following daily oral administration of 0.07 to 0.14 mg/kg enalapril maleate. At steady state, the mean effective half-life for accumulation of enalaprilat was 14 hours and the mean urinary recovery of total enalapril and enalaprilat in 24 hours was 68% of the administered dose. Conversion of enalapril to enalaprilat was in the range of 63 to 76%. The overall results of this study indicate that the pharmacokinetics of enalapril in hypertensive children aged 6 years to ≤16 years are consistent across the studied age groups and consistent with pharmacokinetic historical data in healthy adults. Hypertensive children aged 2 months to 6 years required higher weight-based doses (0.13 mg/kg and 0.11 mg/kg) compared to the older age groups (0.11 mg/kg and 0.07 mg/kg), to achieve similar steady-state AUC.

In the above pediatric study, enalapril maleate was given as tablets and for those children and infants who were unable to swallow tablets or who required a lower dose than is available in tablet form, enalapril was administered in a suspension formulation.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

There was no evidence of a tumorigenic effect when enalapril was administered for 106 weeks to male and female rats at doses up to 90 mg/kg/day or for 94 weeks to male and female mice at doses up to 90 and 180 mg/kg/day, respectively. These doses are 26 times (in rats and female mice) and 13 times (in male mice) the maximum recommended human daily dose (MRHDD) when compared on a body surface area basis.

Neither enalapril maleate nor the active diacid was mutagenic in the Ames microbial mutagen test with or without metabolic activation. Enalapril was also negative in the following genotoxicity studies: rec-assay, reverse mutation assay with *E. coli*, sister chromatid exchange with cultured mammalian cells, and the micronucleus test with mice, as well as in an *in vivo* cytogenic study using mouse bone marrow.

There were no adverse effects on reproductive performance of male and female rats treated with up to 90 mg/kg/day of enalapril (26 times the MRHDD when compared on a body surface area basis).

13.2 Animal Toxicology and/or Pharmacology

In several experimental published studies, rat pups exposed to daily enalapril from birth to post-natal Day 13 (the period of nephrogenesis in this species) developed irreversible renal toxicity. In contrast, treatment after post-natal Day 14 was not toxic to the more mature kidney. Rat kidney development at birth and at 14 days is similar to the human at mid-trimester and in infancy, respectively. The toxic dosages in these studies were about 10X, on a mg/m ^{2} basis, the highest recommended oral (0.58 mg/kg/day) pediatric dosages to treat hypertension. Lower dosages were not studied.

14 CLINICAL STUDIES

14.1 Heart Failure, Mortality Trials

In a multicenter, placebo-controlled clinical trial, 2,569 patients with all degrees of symptomatic heart failure and ejection fraction ≤35 percent were randomized to placebo or enalapril and followed for up to 55 months (SOLVD-Treatment). Use of enalapril was associated with an 11 percent reduction in all-cause mortality and a 30 percent reduction in hospitalization for heart failure. Diseases that excluded patients from enrollment in the study included severe stable angina (>2 attacks/day), hemodynamically significant valvular or outflow tract obstruction, renal failure (creatinine >2.5 mg/dL), cerebral vascular disease (e.g., significant carotid artery disease), advanced pulmonary disease, malignancies, active myocarditis and constrictive pericarditis. The mortality benefit associated with enalapril does not appear to depend upon digitalis being present.

A second multicenter trial used the SOLVD protocol for study of asymptomatic or minimally symptomatic patients. SOLVD-Prevention patients, who had left ventricular ejection fraction ≤35% and no history of symptomatic heart failure, were randomized to placebo (n = 2,117) or enalapril (n = 2,111) and followed for up to 5 years. The majority of patients in the SOLVD-Prevention trial had a history of ischemic heart disease. A history of myocardial infarction was present in 80 percent of patients, current angina pectoris in 34 percent, and a history of hypertension in 37 percent. No statistically significant mortality effect was demonstrated in this population. Enalapril-treated subjects had 32% fewer first hospitalizations for heart failure, and 32% fewer total heart failure hospitalizations. Compared to placebo, 32 percent fewer patients receiving enalapril developed symptoms of overt heart failure. Hospitalizations for cardiovascular reasons were also reduced. There was an insignificant reduction in hospitalizations for any cause in the enalapril treatment group (for enalapril vs. placebo, respectively, 1,166 vs. 1,201 first hospitalizations, 2,649 vs. 2,840 total hospitalizations), although the study was not powered to look for such an effect.

The SOLVD-Prevention trial was not designed to determine whether treatment of asymptomatic patients with low ejection fraction would be superior, with respect to preventing hospitalization, to closer follow-up and use of enalapril at the earliest sign of heart failure. However, under the conditions of follow-up in the SOLVD-Prevention trial (every 4 months at the study clinic; personal physician as needed), 68% of patients on placebo who were hospitalized for heart failure had no prior symptoms recorded which would have signaled initiation of treatment.

The SOLVD-Prevention trial was also not designed to show whether enalapril modified the progression of underlying heart disease.

In another multicenter, placebo-controlled trial (CONSENSUS) limited to patients with NYHA Class IV congestive heart failure and radiographic evidence of cardiomegaly, use of enalapril was associated with improved survival. The results are shown in the following table.

CONSENSUS Survival Rates

	SURVIVAL (%)	
	Six Months	**One Year**
VASOTEC (n = 127)	74	64
Placebo (n = 126)	56	48

In both CONSENSUS and SOLVD-Treatment trials, patients were also usually receiving digitalis, diuretics or both.

16 HOW SUPPLIED/ STORAGE AND HANDLING

Enalapril maleate oral solution is a ready-to-use solution that contains 1 mg/mL of enalapril maleate, USP. It is a clear, colorless oral solution with a mixed berry flavor, packaged in a 150 mL, white, round, high-density polyethylene bottle with a white, polypropylene, child-resistant cap and placed in a carton with tamper-evident seal. Each bottle contains 150 mL.

NDC 69452-237-46

Store refrigerated (2° to 8°C/36° to 46°F) in a tightly closed container. Protect from freezing and excessive heat. Patients may store enalapril maleate oral solution at room temperature (20° to 25°C/68° to 77°F) for up to 60 days.

17 PATIENT COUNSELING INFORMATION

- **Pregnancy**

Tell female patients of childbearing age about the consequences of exposure to enalapril during pregnancy. Discuss treatment options with women planning to become pregnant. Patients should be asked to report pregnancies to their physicians as soon as possible.

- **Angioedema**

Angioedema, including laryngeal edema, may occur at any time during treatment with angiotensin-converting enzyme inhibitors, including enalapril. Advise patients to report immediately any signs or symptoms suggesting angioedema (swelling of face, extremities, eyes, lips, or tongue, or difficulty in swallowing or breathing) and to consult with the prescribing physician before taking more drug.

- **Hypotension**

Caution patients to report lightheadedness, especially during the first few days of therapy. If actual syncope occurs, tell patients to discontinue the drug until they have consulted with the prescribing physician.

Tell patients that excessive perspiration and dehydration may lead to an excessive fall in blood pressure because of reduction in fluid volume. Other causes of volume depletion such as vomiting or diarrhea may also lead to a fall in blood pressure; advise patients to consult with their physician.

- **Hyperkalemia**

Tell patients to consult their physician prior to using salt substitutes containing potassium.

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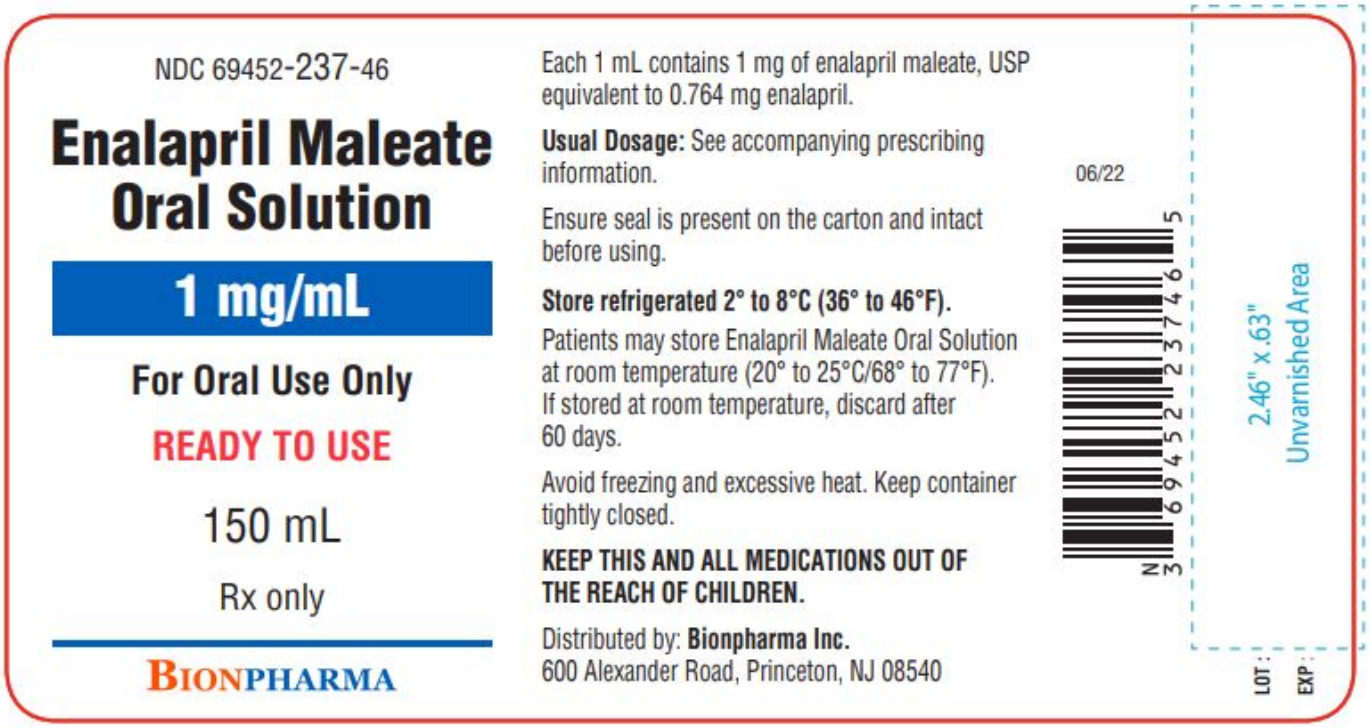
FDA-04

April 2022

PRINCIPAL DISPLAY PANEL - LABEL



PRINCIPAL DISPLAY PANEL - CARTON

ENALAPRIL MALEATE ORAL SOLUTION

enalapril maleate solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69452-237
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ENALAPRIL MALEATE (UNII: 9O25354EPJ) (ENALAPRILAT ANHYDROUS - UNII:Q508Q118JM)	ENALAPRIL MALEATE	1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
BERRY (UNII: FV3431923Z)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69452-237-46	1 in 1 CARTON	08/11/2021	
1		150 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA212408	08/11/2021	

Labeler - Bionpharma Inc. (079637826)

Registrant - Bionpharma Inc. (079637826)

Establishment

Name	Address	ID/FEI	Business Operations
Novitium Pharma LLC		080301870	manufacture(69452-237)

Establishment

Name	Address	ID/FEI	Business Operations
CoreRx Inc.		780516717	manufacture(69452-237)